

Appendix
Volume II

The Belmont Report

Ethical Principles
and Guidelines for
the Protection of
Human Subjects
of Research

The National Commission
for the Protection of Human Subjects
of Biomedical and Behavioral
Research



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Ethical Principles
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The National Commission
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of Biomedical and Behavioral
Research

This Appendix contains (in two volumes)
the full text of the papers that were prepared
to assist the Commission in its consideration
of the basic ethical principles that should
underlie the conduct of research
involving human subjects.

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III

BOUNDARIES BETWEEN RESEARCH AND PRACTICE

PROTECTION OF THE RIGHTS AND INTERESTS
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SURVEY RESEARCH, SECONDARY ANALYSIS OF
RESEARCH DATA, AND STATISTICAL ANALYSIS OF DATA
FROM ADMINISTRATIVE RECORDS

Donald T. Campbell, Ph.D.

and

Joe Shelby Cecil, Ph.D.

Protection of the Rights and Interests of Human Subjects in the Areas
of Program Evaluation, Social Experimentation, Social Indicators,
Survey Research, Secondary Analysis of Research Data, and
Statistical Analysis of Data From Administrative Records

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An important task facing the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research is the establishment of standards for the burgeoning new areas of program evaluation, social indicators, and related activities (to be collectively designated "program evaluation" in this manuscript unless greater specificity is needed). All of these activities are "research" (usually behavioral research) in the sense of Public Law 93-348; thus they fall within the scope of the commission's assignments. As Institutional Review Boards become increasingly involved in approving such research, they could benefit from guidelines prepared by the NCPHSBRR for this novel set of problems.

While the participants in such research clearly have rights and interests which may be violated, the nature of these threats is somewhat unique. Rarely will risk to physical health be involved. Indeed, the experimental group participants often receive an apparent boon which the control group participants may well feel they equally deserve, so that control group rights may often be the greater problem. The more frequent danger in program evaluation is the risk that the research data will be misused since sensitive information is often collected. Such data may be subpoenaed by prosecutors searching for evidence of crimes, or become a source of malicious gossip or blackmail. Federally funded program evaluations frequently require auditing, verification, and reanalysis. These activities may preclude a promise of complete confidentiality to the respondents and increase the risk that the information they provide will be used improperly. However, if respondents are fully informed of these risks, the quality of the research data may be diminished. From these few examples it is apparent that these areas of social research present a different set of problems from those encountered in medical and laboratory research.

This problem area has already received attention from several national organizations. For instance, the Social Science Research Council's Committee on Social Experimentation considered these issues at length over a four-year period, producing a short chapter on "Human Values and Social Experimentation" (Riecken, Boruch, et al., 1974, pp. 245-269). The contemporaneous National Academy of Science - National Research Council "Committee on Federal Agency Evaluation Research" addressed these issues in its report entitled Protecting Individual Privacy in Evaluation Research (Rivlin, et al., 1975). (One of the present authors participated in both of these committees.) The Privacy Protection Study Commission, established by the Privacy Act of 1974, has extensively considered the problem of maintaining confidentiality of research information (Notice of Hearing and Draft Recommendations: Research and Statistics, January 6, 1977). The Social Science Research Council has a longstanding committee

and special staff devoted to Social Indicators, and is establishing a new committee on program evaluation. The Brookings Panel on Social Experimentation recently published a series of papers on this topic (Rivlin and Timpane, 1975). Special committees with this concern exist in many professional organizations. This recent activity provides the National Commission with a unique opportunity to integrate these diverse findings into a general code protecting the rights of subjects participating in these new areas of research.

Background Comments:

Like the others who have agreed to write background papers for the Commission, the present writers have volunteered to do so because of strong concerns on this matter. In these areas of research, two widely cherished values are in potential conflict. The subject's right of privacy may conflict with the researcher's need to gather sensitive information necessary for meaningful program evaluation. We wish to make explicit our manner of resolving this conflict. In agreement with the dominant mood in Washington, we recognize the right to privacy of individuals participating in these areas of research. This paper includes several suggestions which would result in increased protection for the privacy of research participants. However, our greater fear is that Congress and the administration will needlessly preclude important program evaluation and access to research information through ill-considered efforts to protect individual privacy. For example, special procedures of file linkage permit inexpensive and highly relevant program evaluation. Although these procedures require the retrieval of administrative records, they may be employed without jeopardizing the privacy of program participants. (The case for such procedures will be presented in the context of specific recommendations.) We urge that special caution be exercised to avoid creating rules that unnecessarily restrict these procedures.

Before providing our recommendations we wish to set the scope of this report by defining some of the major terms that will be employed:

Program Evaluation: Assembly of evidence bearing on the effectiveness and side effects of ameliorative programs, social innovations, etc. These programs have usually been initiated by governments.

Social Indicators: Statistical summaries, often in time-series form, bearing on the well-being of the nation or smaller social units. Social indicators may be viewed in contrast to more common economic indicators. Many social indicators are generated from statistical summaries of administrative records. Others, such as indicators based on the Census, are produced by institutionalized survey procedures. Increasing attention is being given to "subjective" social indicators, in which representative samples of the public report on their "happiness" or satisfaction with various aspects of their lives in public opinion surveys.

Social Experimentation: This will be narrowly defined, as it was in the SSRC volume (Riecken, et al., 1974), to refer to an experimental form of policy research and/or program evaluation, experiments carried out in social (as opposed to laboratory) settings evaluating governmental or other social interventions. (This definition excludes experiments in public settings to test social science theories, an important form of social experimentation that the National Commission is attending to through other background papers.)

Respondents: Participants, interviewees, anthropological "informants," the persons whose responses are recorded, the "subjects" of research, etc. Many social scientists prefer the terms "respondent" or "participant" to the term "subject," since the term "subject" has been associated with an exploitative attitude neglecting the rights and interests of the research cooperator.

Statistical Data: The Privacy Act of 1974 uses this term to refer to information collected originally for research rather than administrative purposes. This usage will be avoided here in favor of research data.

Statistical Analysis, Statistical Product, and Statistic: These terms refer to summary indices no longer containing individually identifiable data that may be based on either research data or administrative records. Means, standard deviations, correlation coefficients, t ratios, F ratios, probability levels, etc., exemplify statistical products. Frequency counts and percentages usually qualify as statistical products precluding individual identification, but not if the identities of individuals can be deduced through association of research data with public records.

Administrative Records: Refer to data collected originally for bureaucratic purposes rather than research purposes. School grades, achievement test scores, earnings subject to withholding tax, unemployment insurance payments, days hospitalized, incidence of serum hepatitis, auto insurance claims, all represent administrative records that can be of great value in program evaluation if they are used in ways safeguarding individual privacy.

Record, File, Data Bank: These are terms used for collections of data on individuals, either administrative or research data.

Reanalysis and Data Analysis by Outsiders: Refer to the use of research data or administrative records for purposes other than were originally understood by the respondents, and by persons other than the regular custodians of the data.

File Merging: Refers to combining individual data from two files containing data about the same respondents, so that one or both of the files, or a third file, ends up containing individually identified data originating in another file. Unified data banks involve file merging.

File Linkage: Refers to linking data from two or more files so that statistical products are generated involving data from both files. File merging is the most complete form of file linkage, and where permissible, the most statistically efficient. It is important to note, however, that there are restricted forms of file linkage that do not involve file merger, and where no individually identified data are transferred from any file to any other (e.g., the "mutually insulated" file linkage to be discussed below).

Recommendations:

1. Review and Review Boards

Let us start with a concrete recommendation:

1a. *Evaluation research, social indicator research, social survey research, secondary analysis of research data, and statistical analysis of data from administrative records, are to conform to rights of subjects legislation (in particular, PL93-348) and to the guidelines and regulations developed to implement these laws by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This coverage includes all such research regardless of auspices or funding: private, unfunded, university-related, profit and nonprofit research groups, research by governmental employees, etc.*

There is general agreement that these areas of research are and should be covered by PL93-348 and other rights-of-subjects legislation. Probably 99% of such research already is conforming to such standards in the sense of not violating the rights-of-subjects specified. There are essentially no publicized cases of violations in these areas. The problem raised by PL93-348 is the monstrous bureaucratic burden of requiring this vast area of low-risk research to go through formal institutional review processes. (See the two Appendices that present reactions to an earlier draft of this report.) In response to this problem, we are suggesting a process of conditional clearance by affidavit. This procedure provides an expeditious means of reviewing certain low-risk research areas. Sample verification, such as is done for income tax reports, and the threat of subsequent prosecution for actions in violation of the clearance affidavit should discourage abuses. The suggested procedure will be superior to the kind of mass-produced perfunctory clearance that institutional Review Boards would tend to employ in these areas. If affidavit clearance requires a revision of PL93-348, or other laws, we recommend such revisions be enacted.

1b. Rights of Subjects Clearance Procedures: Conditional Clearance by Affidavit and Full Review by Institutional Review Boards. Before soliciting funding or initiating a research activity in the low-risk areas of evaluation research, social experimentation, social indicator research, social survey research, secondary analysis of research data, or statistical analysis of data from administrative records, the Principal Investigator(s) should file with the Institutional Review Board concerned with protecting the rights of the participants in the planned study, a full research proposal and a "clearance affidavit," constituting a detailed affirmation that the rights of the participants and subjects are not jeopardized in any of the ways specified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in implementing PL93-348. At the discretion of the Review Board and the request of the Principal Investigator, this affidavit may constitute a conditional rights-of-subjects clearance, permitting funding requests and research to proceed forthwith, unless or until the Principal Investigator, the Institutional Review Board, or the funding source, requests delay for a full review by the Institutional Review Board. The Institutional Review Board may conduct such a full review at any time during a research proceeding under conditional affidavit clearance, and may order the cessation of research found to be violating rights-of-subjects regulations.

We envisage this conditional clearance by affidavit, for these low-risk areas of research, being implemented through a long, detailed question-

naire that the Principal Investigator(s) would fill out, sign, and have notarized. The contents of the questionnaire would be based on the rules, issues, and guidelines that the National Commission on Protection of Human Subjects of Biomedical and Behavioral Research is now developing, including regulations such as those suggested below. These affidavits and research proposals would be kept on file by the Review Board for the length of the research project and the subsequent period of project liability for participant injury. For these designated low-risk areas, the funding and/or research process could proceed as soon as the proposal and clearance affidavit were filed, if the Principal Investigator(s) had affirmed it as lacking in participant jeopardies and did not wish a Board review. The Board would have the right to examine these on a spot-check, sample, or systematic basis, and to request at any point the cessation of activity (funding applications, data collection, data analysis, etc.) until a Board clearance had been achieved. For these low-risk areas such a delayed decision to hold full review or a veto of the research would be rare, and it would be upon such an estimate and understanding of the regulations that a principal investigator would opt for conditional affidavit clearance rather than requesting a full Board review. Certainly a Board would want to have a staff or Board member examine each affidavit for combinations of features that might indicate possible risks. Since sampling is an efficient technique for quality control, perhaps a Board should give full review to a random one-tenth of conditional affidavit clearances.

From the investigator's point of view, affidavit clearance prolongs the project's vulnerability to a negative Review Board decision and may increase its liability to legal damage claims brought against it by participants. The relative advantage of prior Board clearance may easily be overestimated however. Even for projects they have approved, Review Boards will want the right to determine that the project is restricting itself to the approved activities, and will use that right if it receives complaints.

Consideration should be given to the effects of including program evaluation, etc., on the constitution of Review Boards. This raises a number of problems that were not fully presented in the initial draft of this paper and thus have not received comments. One recommendation is obvious:

1c. Rights-of-Subjects Review Boards should be available to handle program evaluation, etc., on research done by independent investigators, profit and nonprofit research organizations, governmental agencies, etc., as well as for research conducted through universities.

Note that while the Statistical Policy Division of the Office of Management and Budget reviews questionnaire forms for governmental and government contract research, and may consider respondents' rights in the process, this does not necessarily provide the equivalent of Institutional Review Board clearance.

The proper location of these Review Boards becomes a problem. It would be desirable for them to be locally available to the research participants so that complaints can easily be placed and heard. This role for Review Boards becomes particularly important in monitoring the conditional affidavit clearance procedure.

To date, Institutional Review Boards have been set up in the institutions doing the research. Since most of this research has been conducted in universities and hospitals, the participants in such research have had easy access to the Board. However, a program evaluation may be conducted by a more distant institution. Thus local institutions (such as public schools) whose members are frequent subjects of evaluation research may wish to set up their own Rights-of-Subjects Review Boards.

Local Review Boards seem impractical for broad public opinion surveys. While city, county, and state boards are conceivable, and should be given jurisdiction if they request it (local jurisdictions that require licensing of opinion survey interviewers could insist on approval by Review Boards), it would be unreasonable to require local Review Boards for national surveys interviewing only a few people in any one local jurisdiction. For these, a national Review Board is necessary.

Enforcement of the review requirement will be most effective when tied to funding. This suggests that each major source of funding, government and private, set up review boards. While some commercial and private political opinion research may avoid review, this may be the practical limit of the enforcement power. Opinion survey interviewing merges into investigative interviewing by journalists, detective work, credit investigation, neighborly curiosity, and intelligence activities more generally. It is in these areas that Rights-of-Subjects are in the most jeopardy (persons interviewed about as well as persons interviewed) yet we are unlikely to see such "research" activities subject to Rights-of-Subjects scrutiny.

1d. Where there are several Institutional Review Board appropriate, one review is sufficient if the Review Board most directly responsible for the well-being of the respondents does the review or formally concurs in the review.

Research by a university team on hospital patients would provide one example. In such a case, the hospital has the primary responsibility for the well-being of the participants. If a community drug abuse abatement agency required data from high school students to be collected through the schools, and if the school district had a Review Board, it would be the one with the primary responsibility for protecting respondent rights.

To adequately protect research participants' rights, it would seem essential for the participants to know the extent of their rights and where to complain if they feel their rights are in jeopardy. Fully informed research participants will be necessary to monitoring the conduct of research approved under the conditional clearance procedure:

1e. Research participants should each be given a printed statement informing them that the research is being conducted in conformity with Congressional legislation on the rights-of-subjects, the extent of their rights under this legislation, and providing the address and telephone number of the Review Board to whom complaints should be directed.

In the case of a national Review Board, this might include a Toll-Free 800 area code number. This recommendation is one of several that could be implemented with a statement in writing that could be left with the respondent.

Does the inclusion of program evaluation, survey research, etc., have any special implications for the selection of Review Board members? A recommendation characteristic of these areas of research would be that Review Boards contain members of the groups from which participants are being drawn, or, in the case of children, parents of such participants. Such suggestions arise out of experience with ghetto neighborhood boycotts of survey research. It is probably generally true that on these research topics potential participants are more competent to judge when their own interests are threatened than in the case of medical research. A brief training program could supply what technical knowledge would be necessary to make an informed judgment. While we concur in the desirability of having such persons on Boards, along with substantial proportions of nonresearchers, we have been unable to develop a recommendation that would insure such representation and still be feasible. It is difficult to develop a method that would insure representation of the interests of the members of the community while limiting the intrusion of narrow political issues into the review process. If such community representatives were given veto power, this would in effect recognize class or category rights, which is recommended against in section 7.

2. The Borderline Between Administrative Reports on Social Service Delivery and Program Evaluation

There is a problem of borderlines between a social work department delivering its regular services and a similar department testing out new procedures or giving a special evaluation to its standard method of operation. Similarly, there is a borderline between the regular instructional activities in a school and the comparative evaluation of alternative practices. Thus parallels exist to the troublesome problem the Commission faces with regard to medical practice: When does the doctor's exploration of alternative therapies with his patient become research? While the Commission should take some cognizance of the borderlines for program evaluation, these problems seem less serious than those in medical research, and it is probably wise to employ a narrow definition of program evaluation to minimize the coverage. (For cautions and dissensions on this, as related to specific recommendations to follow, see the Appendix A, reactions to points 5-8.)

Social service programs, employment offices, adult education programs, schools, police departments, administrative agencies of all kinds, have in the past had wide latitude in varying their modes of operation. It would seem unwise to add regulations curtailing this freedom, or adding to the bureaucratic difficulties of initiating change. Thus it might be necessary to distinguish between variations in the services and variations in the information collection activities:

2a. Changes in mode of operation of a service agency that are within the legal or customary latitude for change enjoyed by the agency will not be interpreted as research under the purview of the Commission and related statutes, except with regard to any novel data collection activities initiated for the purpose of evaluating the change as a program alternative capable of being adopted by other similar units.

There is an ambiguous borderline between information collected for use

in an annual report of an operating agency and that collected for a program evaluation done by an in-house staff. Clearly it would be unwise to include annual reports or even special-topic operational analyses done to monitor regular operations:

2b. Data collection and analysis done by an institution for operational monitoring of its own operations (as opposed to evaluating program alternatives as policy items capable of being disseminated to other units) will not be regarded as research for the purposes of this Commission and the related laws.

These proposed regulations have obvious ambiguities, but rather than suggest specific refinements, it seems better to wait, allowing operating agencies to define their activities as they choose until specific problems emerge. We must remember that there are Rights-of-Participants issues in every social institution and profession, public and private, whether doing research or not, and this Commission must avoid taking on this whole responsibility.

Expressed purpose in the funding of programs may provide guidelines:

2c. Where funds are specifically designated for evaluation of program effectiveness, construction of social indicators, statistical analyses of administrative data, etc., the activities undertaken with these funds are "research" that should receive clearance as to protection of rights-of-participants in research from an Institutional Review Board.

This proposed regulation does not cover the treatment involved (although 2d below does) but merely the data collection introduced for the evaluation. Such an emphasis contrasts with medical therapies, where the dangers of the treatment are usually the major concern of an Institutional Review Board.

Consider a borderline case like "Title I" programs of compensatory education in public schools. In this massive national program, all districts and schools meeting specified poverty criteria are eligible to receive funds to spend on a variety of special remedial activities of their own devising or choosing, but limited to children designated as educationally deficient. While a great diversity of innovative and traditional remedial activities are involved, these are still within the range of standard operating procedures, and the program is funded as a nationwide activity, not a pilot program. However, where Congress and the Office of Education fund scientific evaluations of the effectiveness of a sample of Title I programs, employing new data collection activities, opinion surveys of parents, students, and school personnel, specifically administered achievement tests, etc., these latter are judged "research" for present purposes.

There are, however, instances in which the treatment as well as the informational research procedures should be reviewed.

2d. Where the enabling legislation specifies a trial or experimental pilot program or demonstration project as well as an evaluation budget; where the research contract or grant funding covers funds for treatment development and treatment delivery as well as

for evaluative information collection, Institutional Review Boards should review the treatment as well as the informational research activities of the project.

Usually the contract RFP's (Requests for Proposals) and grant applications will provide adequate grounds for determining this. While the illustrations have involved governmental programs, privately supported programs also come within the scope of the recommendations.

3. Informed Consent - General

The blanket inclusion of "behavioral research" in PL93-348 may make particularly marked changes in extending the concept of informed consent from laboratory research into areas such as program evaluation and survey research. These effects may be so marked as to result in considerable opposition from the research community. However, the principle is so obviously fair that we recommend the endorsement of this extension.

- 3a. *Individually identifiable participants in social research, surveys, program evaluation, etc., must be informed:*
 - 3a-1. *that research is being conducted;*
 - 3a-2. *of the procedures they will be experiencing;*
 - 3a-3. *of the risks and benefits reasonably to be expected;*
 - 3a-4. *of the purpose of the research;*
 - 3a-5. *of the anticipated uses of the information;*
 - 3a-6. *of the names, addresses, and telephone numbers of the researchers;*
 - 3a-7. *of the names, addresses, and telephone numbers of the sponsors of the research;*
 - 3a-8. *that they are free to ask questions and may refuse to participate; and,*
 - 3a-9. *that they may later withdraw from the research, and the consequences of such withdrawal (cancellation of income subsidies, etc.).*
- 3b. *The exact wording of these statements must be approved by the Rights-of-Subjects Review Board. The Board may approve modifications of the elements of the informed consent agreement when:*
 - 3b-1. *the risk to a subject is minimal;*
 - 3b-2. *rigid adherence to the specified elements of the informed consent agreement undermines important objectives of the research; and*
 - 3b-3. *any reasonable alternative means for attaining these objectives would be less advantageous to the participants in the research.*

The elements of this informed consent agreement are similar to the current HEW informed consent regulation used predominantly in biomedical and clinical psychological research. (For a discussion of the problems raised when the current HEW regulations are extended to social research, see the position paper written for the National Commission by Richard A. Tropp.)

However, certain elements have been added to accommodate special problems that arise in the context of surveys, program evaluation, etc.

Informed consent must be obtained only from "individually identifiable participants" in social research. This limitation results in a fairly narrow definition of "subject at risk" as the term is used in the current HEW regulations. For example, restriction of the informed consent requirements to "participants" in the research will not require the researcher to obtain the consent of nonparticipants who might be affected by the treatment, such as landlords in a housing allowance experiment. Restriction of the requirement to "individually identifiable" participants would exempt anonymous observational studies, etc., in which no jeopardy to the rights of the individual participants exists. In rare instances this narrow definition of "subjects at risk" may be inadequate, such as in research based on hearsay information concerning identifiable individuals. In such rare situations, as in instances of anonymous participants and nonparticipants who may be affected by the research, the broad representation of interests on the Rights-of-Subjects Board should insure that the rights of those whose consent is not required will be respected.

Even with this narrow definition of "subjects at risk," major changes in the conduct of social research would result. Social researchers will be explicitly required to obtain some kind of informed consent of participants. Opinion surveys would be required to identify the sponsors and purposes of the survey, as well as the research firm conducting the survey. (Note that the requirements of information regarding the sponsor's identity (3a-7) and the purpose of the research (3a-4) in the previous draft failed to receive the endorsement of the majority of commentators. Appendix A, Recommendation 24.)

In keeping with the recommendations of Section 5 below, the statements of the purpose of the research (3a-4) may stop short of telling the participants of experimental treatments that they are not receiving. Even so, such information may influence the degree of cooperation by participants, and, even more likely, modify the responses given. It is this latter effect that will most disturb the social research profession. However, data collected under these conditions can be almost as useful as present surveys. It is comparative differences under common contexts that are most informative. Present surveys do not provide "absolute" opinions, but rather opinions conditioned by a heterogeneous set of respondents' surmises and suspicions on the very issues that this recommendation would make explicit. Of course, the more explicit nature of this information may result in greater attention by respondents to these issues, and researchers should anticipate the resulting biases.

In major experiments such as the New Jersey Negative Income Tax Experiments, participants are asked to sign a written consent form. Such formality is usually missing from survey research, even in panel studies where repeated interviews are envisioned. This recommendation anticipates that in most instances, the written consent of the participant must be obtained. In situations such as in telephone surveys, where it would be difficult or awkward to obtain written consent, some other means of obtaining consents will be permitted. However, researchers must always bear the burden of showing that the individual was properly informed and consented to participation in the research, and therefore may wish to require a signed consent form for their own protection.

It has been suggested (see Appendix A, page 8 ,)that separate consents be solicited for the experimental treatment and information collection components of social research. Such separation can improve the control and estimation of attrition bias (Riecken, et al., 1974, 58-59). For the most part, in program evaluation, social indicators research, etc., and for control groups in experiments, only informational consent forms will be required.

Recommendation 3b permits the Rights-of-Subjects Review Board to modify the elements of the informed consent requirements when the risks to the subjects are minor and information regarding one or more of the elements of informed consent would undermine some important research objective. This recommendation is similar to the modification clause in the HEW regulations, and permits the flexibility to accommodate a wide range of social research settings. In certain extreme instances, such assessment of the impact of Title 1 funding, consent of the participants in the research (consent by the parents of the school children) may be waived by the Rights-of-Subjects Review Board. Such a waiver would be appropriate when an institution rather than an individual is the focus of the study. In such a situation a similar informed consent can be obtained from an institution representing the interests of the participants (such as a school board or local governmental body).

Some issues of informed consent in social research are left open by this recommendation. It does not address the problems of gaining consent from special or institutionalized participants (children, prisoners, mental patients). These topics are discussed in other papers submitted to the National Commission.

These proposals on informed consent have not been reviewed in their present form by our cooperating readers, and should be regarded with more caution than the better-tested sections of this paper. Moreover, insofar as the content of these recommendations was covered (Appendix A, Recommendation 24) no favorable consensus was found.

4. Rights and Interests of Respondents in Informational Surveys

A major part of social and behavioral research involves soliciting information from and about respondents by interviews and questionnaires. Respondents certainly have interests and risks with regard to information about themselves that they have provided. Their interests should also be recognized in determining the proper uses of any information that they have provided if it is used in ways identifying them as the source. They also have rights over information that others have provided in which they may have been identified. (It will be argued below that they have no rights that are jeopardized in transfers and uses of such data in which their identification as a source or target is precluded.)

The Rights-of-Subjects in survey research, polling, and interviewing have received relatively little attention compared to the attention these issues have received in other areas of research and record systems. While this overview will touch on these problems, it is necessarily limited in its coverage. If the National Commission agrees that these problems fall within its purview, a special paper centering on the opinion survey industry is called for.

The data solicited by interview and questionnaire for program evaluation, and social indicator development (or for descriptive surveys serving social science or journalistic purposes) often involves information about illegal acts. In addition to indicating obvious criminal behavior, information about income and income sources may indicate violation of tax or welfare laws. Other sensitive information that could result in personal embarrassment or discomforts to the respondent may be solicited.

The procedures of survey sampling make the identity of the respondent known to the interviewer in door-to-door and telephone surveys. Procedures for checking on the honesty and accuracy of interviews through reinterviewing a portion of the respondents require recording this identity, as do research procedures involving reinterviews of the same respondents (e.g., pretests and posttests) or linking respondents to program treatments and other information sources.

Subpoena and Government Audit. The Mercer County prosecutor requested information about the participants in the New Jersey Negative Income Tax Experiment (Watts & Rees, 1973) as a part of a broad search for cases of welfare cheating. The power of governmental agencies to legally subpoena such information creates a real jeopardy to participants in much social research. The decennial census and the interim sample surveys conducted by the Bureau of the Census are made exempt from such subpoena by acts of Congress. Certain enabling legislation in drug abuse research has empowered the Secretary of HEW to give such immunity to specific research projects. But the New Jersey Negative Income Tax Experiment and most program evaluation research lacks such protection. In some cases, researchers have gone to jail or risked going rather than release confidential information, while in other cases, confidential information has been released (Carroll & Knerr, 1976).

In the Mercer County case, the project and the prosecutor settled out-of-court. The project gave the prosecutor names of recipients and amounts of money received from the project, but no information on income or anything else that respondents had provided the project. The present writers believe that this is also the dividing line that any statutes providing privileged communication protection for research data should follow. The actions of government and of research agencies must be subject to freedom of information requirements. The communications of cooperating respondents made for the purpose of providing research information, however, should be privileged communications. If law enforcement groups want this information, they can ask it of the respondents themselves. Nejelski & Peyser (1975) recommend a broader protection, including protection of information about the researcher's actions. However, all agree that such a statute should cover the information in all its data processing stages, rather than just in the interviewer-interviewee communication. Such legislation seems unlikely, and the National Commission on safeguarding research participants' rights will have to set standards that assume subpoena jeopardy.

Required audits of federally sponsored social experiments may result in similar threats to the confidentiality of identifiable information. The General Accounting Office, pursuant to a request from a Senate Committee considering preliminary analyses from the New Jersey Experiment, sought to audit and verify interviews. The project staff gave these auditors full access to the computer data from interviews with individual identifiers deleted, and the

GAO produced its own parallel analyses of income guarantee effects. The staff also permitted GAO access to a sample of individually identified files to audit the accuracy of the transfer from individual files to the record systems used in the analysis which may have been in violation of the project's promise of confidentiality. Such access was sufficient to meet the purpose of the audit without requiring GAO auditors to reinterview the respondents. During 1975 a similar issue has been raised between the GAO and the Housing Allowance Experiment operated by HUD through The Urban Institute, Rand Corporation, and Abt and Associates.

Since, in ordinary public opinion polls, verification by sample reinterview is a standard procedure for checking interviewer honesty and competence, it would seem a desirable feature of government auditing of program evaluation data. Because such data are assembled as a part of a governmental decision-making process, it seems essential that audit, recount, reanalyses, and other verification processes be possible. Theoretically it might be possible to verify sample surveys by selecting and interviewing independent samples of the same size drawn according to the same rules. But since this will rarely be feasible, it seems undesirable to preclude verification contacts with the original interviewees. It also seems undesirable to violate pledges of confidentiality to the respondents. Perhaps slight changes in those pledges so as to mention the rare possibility of verification interviews to check interviewer honesty would suffice without reducing respondent cooperation on sensitive material. If, despite these precautions, the information is so sensitive that the threat of recontact would substantially impair participation in the research, other less intrusive means of establishing response validity should be considered (Boruch & Cecil, 1977).

The possibility of subpoena and of release of names to auditors for research verification interact crucially with informed consent. The Institutional Review Board should examine the specific wordings of the explanation of research purpose and pledges of confidentiality made to respondents. Recommended wordings might eventually be prepared. The risks involved will depend upon the type of information being requested and degree of cooperation promised by local prosecutors and police.

4a. *Where the material solicited involves no obvious jeopardy to respondents, a vague, general promise of confidentiality is acceptable. E.g., "These interviews will be summarized in group statistics so that no one will learn of your individual answers. All interviews will be kept confidential. There is a remote chance that you will be contacted later to verify the fact that I actually conducted this interview and have conducted it completely and honestly."*

4b. *Where full and honest answers to the question could jeopardize a respondent's interests in the case of a subpoena, the respondent should be so informed. E.g., "These interviews are being made to provide average statistical evidence in which individual answers will not be identified or identifiable. We will do everything in our power to keep your answer completely confidential."*

Only if so ordered by Court and Judge would we turn over individually identified interviews to any other group or government agency. We believe that this is very unlikely to happen, because of the assurance of cooperation we have received from _____."

4c. Where the researcher has made the data invulnerable to subpoena, as by not himself having the key linking names to code members, this being stored beyond reach of subpoena or in some agency like the census bureau immune from subpoena, or where the researcher has used other procedural or statistical techniques that insure the anonymity of the sensitive information, the warning of possible subpoena may be omitted from the background statement to the respondent.

The devices are discussed more fully elsewhere (see Boruch & Cecil, 1977, and Campbell, Boruch, Schwartz, & Steinberg, 1977, for a review of this literature). While they have not been tested in the courts, they are probably sure enough, and the dangers of subpoena remote enough, so that omitting mention of the subpoena possibility creates no real jeopardy. In general, as shown in the Appendix (reactions to recommendations 9, 10, and 11) our volunteer panel were favorable to these recommendations, although vigorous comments were generated. A strong minority found 4b not protective enough.

Subpoena is probably a rarer threat than accidental release of individual information in the form of gossip. Blackmail, though a rare event, should also be considered. Thus respondents' rights are involved in the degree to which the data processors have access to the data in an individually identified form. From the COFAER Report (Rivlin, et al., 1975) come these three recommendations that the present authors also endorse.

4d. Sensitive information should not be collected unless it is clearly necessary to the evaluation and is to be used.

4e. Where it is feasible and does not undermine the validity of the evaluation, the anonymity of the respondent should be preserved from the beginning by not collecting identifying information at all.

4f. Identifying information, such as name and address or Social Security number, should be removed from the individual records at the earliest possible stage of analysis and replaced by a code number. The key linking this code number to the identifying information should be stored in a safe place and access to it severely limited. This key should be destroyed as soon as it is no longer needed.

Even with individual identifiers removed, individual data should probably not be stored on time-sharing computer systems, as this makes possible a repeated accessing of the data, utilizing variables that are a matter of public record, so as to break the code for some specific individuals.

5. Rights and Interests of Participants in Social Experiments with Regard to Treatment Variables.

5a. *All participants in an experimental program should be informed in advance of all features of the treatment and measurement process that they will be experiencing that would subject them to any obvious risk or jeopardy and that would be likely to influence their decision to participate in the program or their conduct as participants in the program. Institutional Review Boards should be provided with copies of the statements made to potential participants when seeking their consent.*

All experts would probably concur in this recommendation, even though there will be many settings in which living up to it will produce less valid data than if participants were not informed of certain aspects of the treatment variable, or kept in ignorance of the fact that an experiment was going on. There is a further degree of informed consent, however, that methodologists would recommend against. This is the informing of each group of what the other groups in the experiment are getting, in particular, informing the control group of the desirable treatments the experimental groups are getting. The social experimentation committee of the Social Science Council discussed this issue at length, and ended up approving this position, since the interests of the control group are not jeopardized and since more complete disclosure would have potentially destructive effects on the conduct of the research. For example, in the New Jersey Negative Income Tax Experiment, the control group members were not informed about the maintenance payments of up to \$1000 or \$2000 per year to the experimental group members. As it was, some 26% of the control group were lost from the experiment in spite of the \$15.00 per interview four times a year, while only 7% were lost from the best-paying experimental group. Envy and resentment, coming from awareness of relative deprivation of the control group would almost certainly have added to this differential drop-out rate.

There are cases, to be sure, in which keeping a control group untreated and in ignorance of the availability of the treatment being offered the experimental group represents major deprivation of rights and harm to well-being. The recently publicized experiment on syphilis treatments started in the 1930's in the South is a case in point. When started, the informed consent of the participants should have been secured, but the available "cures" were so ineffective that the use of a control group restricted to traditional treatments was probably not unethical. However, once penicillin became available, the dramatic (even if only quasi-experimental) evidence of its effectiveness and its plentiful availability, made it immoral to withhold it from the experimental group. While a parallel situation is extremely unlikely in the realm of program evaluation, the possibility should be kept in mind.

To return to a discussion of informed consent with regard to experimental treatments, in the New Jersey Experiment, it was recognized as essential that the recipients of the income supports understand clearly that it was for three years only. (This has been the source of such serious criticisms about the validity of the experiment for purposes of extrapolating to the impact of a permanent national program, that in later experiments small groups are getting guarantees of up to 20 years.) Were the experiment to be redone again today, the recipients should be warned that information about the payments made by

the project to them would be released to government officials if requested.

It should also be remembered that many boons are and should be adopted on the basis of a consensus of expert judgment and popular demand. If such a consensus is present, quasi-experimental designs not involving equally needy control groups may have to be used (Riecken, et al., 1974, Chapter IV). If the treatment is in short supply, by making quantitatively explicit the degree of need and assigning to treatment on this basis, an especially powerful quasi-experimental design is made possible (Riecken, loc. cit.).

5b. Where there is already expert consensus on the value and feasibility of a treatment and where there are adequate supplies of the treatment available, needy control groups should not be deprived of the treatment.

It should be noted that pilot programs, experimental programs, and demonstration programs do not come under this exclusion. Such testings of potential policies should be done so as to optimally learn of the social costs and benefits of the program, and this will usually require random assignment of participants to experimental and control conditions. If there is expert consensus on the costs, benefits, feasibility, etc., then the program could just as well be adopted as national policy at once; if controls cannot ethically be deprived of the treatment, then usually the pilot program is not worth doing. However, if no one is to get the experimental boon unless others equally needy are left without it, then the drawing of lots, random assignment, is a traditional equitable method of assigning the boon. In such circumstances, the controls are not being deprived in relation to the general population, but only in relation to the temporary experimental recipients. (This condition definitely did not hold in the syphilis study.)

6. Reanalysis of Research Data and Statistical Analysis of Administrative Records.

Here is an area in which some current interpretations of subjects' rights are needlessly hampering useful science. Let us begin by proposing an exclusionary rule.

6a. The reuse of research data for reanalysis or for novel analyses, and the statistical analysis of administrative records, jeopardize no individual rights as long as no individually identifiable data are transferred out of the file of original custody into another file. For uses and reuses meeting this requirement, the informed consent of the respondents is not required.

There are horror stories about Institutional Review Boards requiring each original subjects' permission for the statistical reanalysis of 20-year old intelligence test data even though names and other identifying information had been deleted from the data. Certainly this seems a totally unnecessary requirement. The Russell Sage Foundation's guidelines for the maintenance of school records (Russell Sage Foundation, 1970) suggests parental approval of each research use of a child's record. Certainly this should be changed to read "for each research use involving the release of individually identified records." The most recent draft recommendations to the Privacy Protection Study

Commission suggest that greater access to records for research purposes be permitted so long as the information is not used to make a determination about any individual (Notice of Hearings and Draft Recommendations: Research and Statistics, January 6, 1977).

As an example of the practice recommended in 6a, data of the New Jersey Negative Income Tax Experiment are now available to social scientists through the Institute for Research on Poverty, University of Wisconsin. From the data have been deleted names, addresses (but not cities), Social Security numbers, names of the family doctor, and a few other specifics that might lead to identification.

6b. Individually identified data (research or administrative) may be released to new users for statistical analysis only with permission of the individual described by and originally generating the data.

While this rule is consistent with the spirit of the Privacy Act of 1974, the draft recommendations of the Privacy Protection Study Commission suggests that the Privacy Act be amended to permit greater access to identifiable research information without the consent of the individual participants. If the act is so amended, we would urge that this proposed rule then be rewritten to permit much greater access to research information.

6c. Release of research or administrative data to new users for statistical analysis when done without the express permission of each respondent must be done so as to adequately safeguard all individual identities.

Procedures for achieving this have been described elsewhere (see Boruch & Cecil, 1977, and Campbell, Boruch, Schwartz, & Steinberg, 1977, for reviews). Usually this would include deletion of the participant's name, address, Social Security number, specific birth date (but not year), specific birth place (but not geographical region). Where some of the research variables are publicly available and can be associated with identifiable individuals (such as lists and descriptions of members of a school or a professional association), it may also be necessary to delete this information or use crude report categories for the variables that are in these accessible lists. Even where multiple tables of frequencies or percentages are presented, rather than individual-level data, detective work may make possible the uncovering of individual identified information. Restrictions on minimal cell frequency and randomized rounding may be required in such cases.

6d. The original custodians of research or administrative data may generate and release to others statistical products in which individual information is not identifiable, including statistical products not anticipated by the individuals initially generating the data.

It is anticipated that in the future the requirements of respondent confidentiality and of hard-headed meaningful program evaluation will be resolved by increasing the data-analysis capabilities of administrative record files. Through the "Mutually Insulated File Linkage" (Campbell, Boruch, Schwartz, & Steinberg, 1977), the records of two files can be

statistically linked without exchanging any individually identified data, thus conforming to this rule. But this procedure requires that the custodial file be able to do standard statistical analyses as well as internal data retrieval for individuals. For many ameliorative programs, government records on subsequent earnings and unemployment compensation would provide accurate and inexpensive measures of effects. While these procedures would have their own problems, almost certainly they would avoid the differential attrition rate found for the interviews in the New Jersey study. Accordingly, it would be in the government's interest to increase the internal data retrieval and statistical analysis capacities of private health insurance, auto insurance, educational testing agencies, hospitals, schools, etc., so that these data could be used in program evaluation and social indicator generation in ways precluding identifying individual data.

For many psychological studies in college settings, it would be desirable to statistically correlate laboratory performance and general intelligence or grade point average from school records. This could be done either with individual permission, or through mutually insulated file linkage, in which regular registrar staff members were paid to work overtime to retrieve the relevant data on specified lists of persons, transform these to means and standard deviations by lists, and then return only these summary statistics by list.

While it is beyond the scope of the National Commission, it should be noted that privacy legislation curtailing the use of Social Security numbers as all-purpose individual identifiers hinders the uses just described. Greater protection of individual privacy can be achieved by prohibiting unified data banks. No abuse of privacy has resulted from the limited use of social security numbers in research. The prohibition of the use of social security numbers for research purposes is a needless and harmful precaution.

7. Future Controversial Issues.

The above sections have hastily sketched some of the major areas of concern that are "timely," in the sense that they are in tune with the concerns of Congress in setting up the Commission, and also represent to a considerable degree an emerging consensus among the quantitative social scientists engaged in program evaluation and social indicator development. (Section 3, Informed Consent, as it affects opinion surveys may have gone beyond this consensus.)

This present consensus, however, may be seen as but the current form of a growing shift in public consciousness about the rights-of-subjects as a part of an increasingly equalitarian participatory democracy. It may help the Commission to consider what the parallel set of demands 10 years hence might also contain. The following three topics are included for this purpose.

Respondents' Interests in the Topics on Which Data are Collected. A recent trend in criticism of research on social problems, including evaluation research, goes under the name "blaming the victim" (Ryan, 1971; Caplan & Nelson, 1973). There is a recurrent option in program evaluation and social indicator research as to whether evidence of a social problem is indexed as an attribute of the individual or as an attribute of the social setting and the social institutions present. When the data are indexed as individual attributes

(ability, morale, personality, employment status) this predisposes the analysis to end up "blaming the victims" of social system malfunction for their lot in life. Many times there are options in the wordings of questions that can make big differences in the social causation implied even while collecting very nearly the same data. Standards could be developed requiring that articulate spokesmen of the program recipient population be asked to check on the research instruments in this regard. Or more specific recommendations could be developed, such as recommending the social setting attributional format wherever the option existed. Shifts of this kind might be of practical value as well. In many urban ghetto settings, opinion surveys meet with mass boycott, greatly hampering the evaluation of new alternatives in social welfare services delivery. In most such instances, the program evaluation purposes would be served just as well by substituting "is this service effective" questions for the "are you sick" questions. The conceptual shift is to turn the welfare recipient into an expert on the quality of welfare services delivered rather than a source of evidence about his own inadequacies. This shift, plus one on rights to the results below, will almost certainly increase the cooperation received, and turn the informational survey into a useful vehicle for communicating neighborhood complaints to government. We have not developed a recommendation in this area, and the reactions of our panel of readers of the earlier draft (See the Appendix, points 21 and 22) shows that no consensus exists to support such a recommendation.

Note that the "blaming the victim" theme is only one illustration of such respondents' interests. The more general class is discussed in the next section.

Class or Category, Privacy, Interests, and Rights. This paper and the National Commissions' activities as a whole have assumed that the rights-of-subjects are individual rights. Jeopardy to the rights of a class or category to which the subject belongs have not been considered. Most discussions of rights-of-subjects join us on this. Class rights are a Pandora's box that, if given recognition, would totally preclude most social science research. The present writers recommend that we continue to refrain from recognizing such rights in research ethics but that we make this decision self-consciously, with some recognition of the issues we are neglecting.

Some examples: The American Council on Education from anonymous surveys of college students prepared a profile of the activist campus radical who had been involved in destruction of property and disruption of speeches, etc. No radical respondent was thereby jeopardized for the past acts confessed to, since the data were genuinely anonymous in their initial collection by mailed ballot. But the interests of current and future radicals are jeopardized. For example, college admissions offices seeking to exclude such students, could do so on an actuarial basis by asking applicants the profile questions about backgrounds, interests, activities, and values, and excluding those applicants who fit the profile with a large proportion of the predisposing signs. In such a case, the proper protection may be to increase the legal accountability of college admissions procedures by prohibiting the use of anything but academic competence criteria. Rules seeking to preclude such class or category jeopardy in research seem to us unacceptable in their likely coverage.

The statistical analyses by the Bureau of Internal Revenue might show that M.D.'s of certain types have twice the income of other professionals. This jeopardizes the interests of these M.D.'s by increasing the frequency with which they are approached by fund raisers, confidence men, and burglars,

and by the invidiously focused zeal of internal revenue agents. Yet such class and category social statistics seem to us absolutely essential for the governance of a democracy in which past governmental decisions are a major determinant of income inequities even in the free market sector of the economy.

Black leaders are justifiably disturbed about social statistics reporting on invidious black-white comparisons in achievement test scores and crime rates. Perhaps even data on income and rental costs could be regarded as prejudicial. Yet these data seem essential background evidence on which to base governmental action seeking to remove the traditional environmental disadvantages blacks live under. The Civil Rights movement has had to reverse itself on this within the last 25 years. For example, in 1950 those working on reducing the de facto segregation in the Chicago schools had as their goal color-blind assignment of children to school districts and setting of school district boundaries. At that time open or disguised records indicated the race of every child and teacher. Within ten years, the Chicago school system was stonewalling those pushing for more integration by asserting that they had no way of telling which teachers and pupils were black. To achieve real integration, racial identification had to be made known and counted by categories. Affirmative action and school integration would be impossible without it.

At the present time, the no doubt environmentally produced black-white difference in school achievement tests has been so redundantly documented and is so regularly misinterpreted as evidence of an innate racial inferiority, that one of us has called for a cessation on all such research unless accompanied by thorough measurement of the black-white differential in opportunities to learn the specific items the tests employ (Campbell & Frey, 1970). Considering the problem of class or category rights as a whole, however, we are reluctant to see any such appeal made a compulsory rule.

Respondent Rights to Data Produced. It will increasingly be argued in the future that the participants in research, the interviewees in public opinion surveys, etc., are co-producers of the research product, and should be co-owners of that product with an equal right to know the results and to use that information in political arguments and in other ways. This could lead to the rule that all respondents to an informational survey should be provided with the statistical results produced. Such a rule could be implemented by having these results placed in the nearest public library to each respondent.

Another way of arriving at such a proposal is to recognize that where such surveys are a part of governmental decision-making, the voting booth rather than the animal laboratory becomes the relevant model. Just as voters get to know and use the results of elections they have voted in, so too they should know the results of surveys and interviews they have participated in. This equalitarian emphasis is supported by an analysis that sees researchers as a potentially self-serving elite who may exploit the cooperative efforts of the respondents by producing products that may be used to harm the interests of the respondents. While in medical and physical research, the results might not usually be meaningful and useful to the respondents, for most social science surveys they would be.

The present writers would be happy to have this adopted right now as standard operating procedure for all public opinion polls as well as evaluation research, including private polls now never published. Along with this would

go full information prior to the questioning as to who was paying for each question and how the information would be used. These rules would decrease the descriptive value of opinion surveys, in that answers would be more consciously given so as to produce politically desired statistical results. However, we believe the trends in political conscience are such that in 10 or 20 years we will have to live with these limitations. (This proposal received a bare majority of endorsements in our volunteer panel, as reported in the Appendix under Recommendation 24.)

Summary

This background paper for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research asserts that research in program evaluation, social experimentation, social indicator research, survey research, secondary analysis of research data and statistical analysis of data from administrative records are and should be covered by PL93-348 and other rights-of-subjects legislation.

Because this vastly increases the burden on existing Review Boards, and because actual cases of abuse of subjects' rights are essentially nonexistent in this area, a procedure of conditional clearance affidavit is suggested that, at the discretion of the Review Board, might substitute for full review in most cases. Greater numbers and new types of Rights-of-Subjects Review Boards will be needed.

Most jeopardies to rights-of-subjects in these areas will come from the information about them that is collected. In the boundary between research and practice, it is recommended that shifts in administrative policy that are normally within an administrator's discretion not be regarded as research, but that novel data collection procedures designed to evaluate such changes be classified as research and subject to Review Board scrutiny.

Extending the right of informed consent into these areas, especially survey research and other information gathering activities, will require major procedural changes that will seem to threaten the validity of results. This extension is nonetheless recommended. Informing respondents of the risks of verificational interviews and of subpoena of information is recommended where these risks exist.

It is recommended that reanalysis of research data and statistical analyses of administrative records be permitted without respondent permission where no individually identifiable data are transmitted out of the original file of custody.

In future decades, issues of class rights, of respondents' interest in question form to avoid blaming the victim, and of respondents' co-ownership of the research results will have to be faced. While the Commission's attention is called to these areas, no formal recommendations are offered.

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Title II of the National Research Service Award Act of 1974 (PL93-348).

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Two appendices to this report are available upon request.

Appendix A (23 pp) provides a summary of the reactions to the 25 recommendations contained in the 3 Jan 76 Draft of this report.

Appendix B (74 pp) provides the full details of the written comments, the names and addresses of those reacting to the 3 Jan 76 Draft, and a list of the lists from which came the 400 names of those asked to comment.

13

RESPONSE TO COMMISSION DUTIES AS DETAILED IN
P.L. 93-348, SEC. 202(a)(1)(B)(i)

Donald Gallant, M.D.

Response to Commission Duties as Detailed in PL 93-348,
Sec. 202 (a)(1)(B)(i)

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Before considering the boundaries between research and therapy in the field of mental health, I should first state that the original charge to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (NCPHSBBR) in Public Law 93-348, Section 202 (a)(1)(B)(i) totally ignored the reality that the present "accepted and routine practice of medicine" is frequently less than adequate in many sections of the United States. Thus, "accepted and routine practice" of medicine by some physicians includes techniques that have not been scientifically proved in a valid manner and could, therefore, be considered research. In many cases, the "accepted and routine practice of medicine" deviates from the "intelligent" practice of medicine to such an extent that the ignorant physician is actually conducting research without the realization that he is utilizing unproved techniques in the treatment of his patient. Excellent examples of this situation are detailed in an article, "The Prescribed Environment," by Dr. Harry Dowling that was published in the Saturday Review of April 3, 1971 (pages 58 through 60). Practices in surgery such as the use of prophylactic antibiotics for inguinal hernia operations are still standard practice in a number of communities; yet this treatment approach is not based on any scientifically valid observations or statistically significant experimental

results, thus placing this "standard practice" in the area of research. This same article refers to a survey of the use of antibiotics in 76 community hospitals in which a review of 85,000 patients' charts showed that only 54 percent of the patients were receiving antibiotics based upon justifiable reasons. Thus, the use of the term "accepted and routine practice of medicine" in PL 93-348 is somewhat misleading and makes it impossible to separate definitions of research from intelligent innovative medical practice or from ignorant medical practice which frequently is "accepted and routine practice of medicine." If this concept of "accepted and routine practice" were allowed to prevail, the eventual accomplishment would be the least common denominator or a relatively uniform standard of mediocre medical practice. Perhaps more appropriate terminology might have been, "the boundaries between biomedical or behavioral research involving human subjects and the competent practice of medicine based upon scientifically valid experimentation."

To reinforce this viewpoint and attempt to show that this is not merely a difference in semantics, it should be pointed out that "blood-letting" was still included in the "accepted and routine practice of medicine" in the early Nineteenth Century. This procedure was still being utilized at that time despite the fact that it was based upon no scientifically valid experiments with controlled observations more than 50 years after Lind had demonstrated the value of controlled experimentation. At present, the same lack of scientifically valid data applies to classical psychoanalysis, encounter group therapy, marathon group therapy, etc. Another example may be seen in surgical practice. Until

recent years, it was the standard practice in this country to use radical mastectomy for the treatment of breast cancer. However, as detailed in the book, Medical Experimentation, by Charles Fried (pages 48 and 49), radical mastectomy does not result in a higher incidence of therapeutic success than simple mastectomy. The use of radical mastectomy in this country was not based upon scientifically valid experimentation but was considered to be part of the "accepted and routine practice of medicine." In research conducted by teams of doctors in Great Britain and Denmark, it was concluded that radical mastectomy was not more successful than simple mastectomy concerning recurrence rate or mortality rate. The use of the term, "accepted and routine practice of medicine," bears the connotation of competent and best available techniques. However, the above examples demonstrate the inadequacies of certain "accepted and routine practices of medicine."

Definitions

This section will define the "competent practice of medicine" and "research." The definition of "accepted and routine practice of medicine" should be based upon the requirement that the therapeutic technique should have been shown to have been more successful in a statistically significant manner than any type of inert (placebo) therapy approach and the benefits of the treatment technique outweigh the risks. This definition of the "competent practice of medicine" enables us to more clearly differentiate research from the practice of medicine. The intent of all legislation should be to improve the welfare of the

community. Thus, the framers of this particular piece of legislation are obligated to upgrade the practice of medicine if they intend to delineate research from the "competent practice of medicine." Present routine or accepted practices of medicine that are not based upon scientifically proved observations should be allowed to continue temporarily, but regulations must be established to require the evaluation of such techniques which have never been shown to be significantly superior to an inactive or inert type of treatment approach.

Biomedical or behavioral research involving human subjects should be defined as well-designed and critical investigations of therapeutic techniques with unknown efficacy and/or risks or an attempt to find the etiology of a disease having for its aim the discovery of new facts associated with the "accepted and routine practice of medicine" with the ultimate goal of providing beneficial effects for human subjects.

A Proposed Method for Delineating "Research" from the "Competent Practice of Medicine" Based Upon Scientifically Proved Experiments

In his paper, Dr. R. Levine raised some important questions about specific problems relating to the boundaries between research and the practice of medicine. Any question of boundaries could be reviewed by a local Extraordinary Treatment Committee (ETC) which would consist of legal advisors and physicians not associated with the clinic or institution. This type of Extraordinary Treatment Committee has been detailed in the Wyatt v. Stickney case, 1972. The first level of the review would

be a local treatment review committee; the next level should be constituted of regional appeal boards; the highest appeal authority would be a national board with the same approximate composition as the local ones but involving persons of national stature, to evolve review standards and clarify the questions. Responsibility for establishing the guidelines for these independent Extraordinary Treatment Committees (ETC) should be assigned to your commission (NCPHSBBR). It is my own personal recommendation that, in addition to the scientists and legal consultants etc., an expert in statistics be assigned to each of these committees. (At present, we are making the same recommendation in regard to the Institutional Review Boards.) Such a committee may be more appropriate for review of the problem under consideration than the Professional Standards Review Committees (PSRO).

In those treatment procedures which are not based upon scientifically significant observations, it is particularly essential that full informed consent be obtained from the patient. The basic elements of this informed consent should be:

- 1) An explanation of the procedures to be followed, including an identification of those which are not based upon scientifically valid observations or statistically significant results and thus are experimental;
- 2) A description of the attendant discomforts and risks;
- 3) A description of the benefits which may be expected;
- 4) A disclosure of appropriate and available alternative procedures that would be advantageous for the patient;
- 5) An offer to answer any inquiries concerning the procedures;

- 6) An instruction to the patient that he is free to withdraw his consent and discontinue the treatment at any time;
- 7) The physician has the continuing responsibility to inform the patient about any significant new information arising from other sources which might affect the patient's choice to continue the treatment;
- 8) In cases where a patient is mentally incompetent or too young to comprehend, informed consent must be obtained from one who is legally authorized to consent in behalf of the proposed subject, (Of course, this type of permission varies from state to state,) However, where the subject is a child who has reached the age of some discretion such as adolescence or if the patient is otherwise mentally competent, the physician should obtain the patient's consent in addition to that of the person legally authorized to consent on his behalf.

Since behavioral therapy, psychotherapy, psychoanalysis, and other types of verbal and physical techniques (as well as pharmacologic medications) may have important consequences for the patient's life, the patient should definitely have the opportunity to obtain adequate information about the proposed treatment technique and then make his or her own judgments whether or not to undergo treatment with a therapeutic technique that has not been scientifically proved to be statistically significant in relation to an inert technique. The Wyatt case has already established this principle with regard to electroconvulsive therapy, aversive conditioning, and psychosurgery. The same principles should be applied to other

types of treatment. The real problem arises with the non-medical person who does not require licensure in his locality to utilize behavioral or verbal techniques with patients. This type of individual would not be subject to the authority of the Extraordinary Treatment Committee; this important gap and potentially dangerous situation must be corrected by the NCPHSBBR.

In addition to having the opportunity to review and reject a treatment program which has not been based upon scientifically valid observations, the patient should also have the opportunity to receive a new medication or innovative treatment approach if previously available scientifically valid techniques have failed. In an opinion rendered by the Attorney-General of the State of Louisiana (Opinion:74-1675, 1974), it is recognized that "patients who are committed to state mental hospitals have a constitutional right to receive such individual treatment as would give each of them a 'realistic' opportunity to be cured or to improve." An Extraordinary Treatment Committee (ETC) should be available to give approval to a physician who wants to increase the dosage of medication for a "drug-refractory" schizophrenic patient above the maximal dosages recommended by the FDA. A readily available ETC would be essential for the innovative, intelligent physician who understands how to apply a variety of pharmacologic techniques or behavioral techniques for the welfare and benefit of the patient. New behavioral therapy approaches or innovative types of group encounter techniques practiced by either physicians or lay therapists would have to be reviewed by the same ETC. Thus, the ETC would require several full-time administrative staff members as well as rotating part-time professional members, since many of the present techniques that

are utilized in psychotherapy and behavioral therapy (as well as in other fields of medical practice) lack scientific validity. It would be too difficult to find competent professional people in the field of medicine who would be willing to serve on a full-time basis on the ETC.

It should be noted that the literature contains a number of valid scientific observations concerning psychotherapy and behavioral therapy. One such article by Sloane et al. (American Journal of Psychiatry 132: 373-377, 1975) reviewed a controlled evaluation of 94 patients with anxiety neurosis or personality disorder who had been randomly assigned for 4 months to a waiting list, behavioral therapy, or psychoanalytically oriented therapy. The two treatment groups improved equally well and significantly more than those on the waiting list at the end of 4 months. However, one year and two years after the initial assessment, all groups including the waiting list group were found to be equally and significantly improved. Thus, the Extraordinary Treatment Committee as well as the Institutional Review Board will have difficult problems in evaluating the acceptable duration of treatment time as well as specific treatment technique. Theoretically, all treatment techniques, including behavioral approaches such as individual therapy, group therapy, encounter therapy, etc. should be based on valid, controlled research data which show the therapy to be significantly superior to non-specific treatment approaches. There is no doubt that this requirement would cause a heavy administrative burden on a local as well as national basis, but this approach should eventually result in maintaining a competent standard for the practice of medicine, and the requirement would help to differentiate more clearly

between research and the competent practice of medicine, as compared to the subjective attempt to understand the physician's "intent" when he uses a scientifically unproved technique to treat his patient.

If one were to accept the legislative assignment to the committee as detailed in Section 202 (a)(1)(B)(i), there would be no other choice than to accept Dr. R. Levine's differentiation between research and the "accepted and routine practice of medicine," which relies mainly upon intent. From this point of view, it would then be impossible to "read" the physician's mind accurately and separate the innovative practitioner of medicine from the researcher. A readily accessible Extraordinary Treatment Committee would be of help to the innovative physician while halting the incompetent physician from continuing an "accepted or routine practice" that has no scientific validity or therapeutic efficacy. A specific recent example of the problems in this area can be seen in the use of propranolol (Inderal) in the United States. Propranolol was approved for use by the FDA for certain types of cardiac conditions but had not been approved for use in hypertension. However, hundreds of United States physicians being familiar with the European literature describing the efficacy of propranolol in patients who presented high blood pressure, were utilizing propranolol for their patients with high blood pressure. When propranolol is used in a sensible manner, it can be of definite help to some patients with hypertension or high blood pressure, and it also is of help to patients who have familial tremor. However, the use of propranolol was not an "accepted and routine practice of medicine;" thus the inference in PL 93-348 would have been that propranolol was being used in a research approach, but this medical

technique would not have been defined as research by Dr. Levine, who recognized that the "intent" was based upon scientifically valid data from Europe and that the physician was not experimenting with the patient but was using propranolol as a therapeutic tool. A readily accessible Extraordinary Treatment Committee (ETC) would have given the practicing physician permission to use propranolol as a therapeutic agent and would not have required the physician to submit a research protocol to the IRB to prove the therapeutic efficacy of the agent which had already been accomplished in Europe. Therefore, the ETC should have individuals who are experts in the various medical research specialities available for ad hoc consultation. The words "available" and "readily accessible" are underlined because these requirements would be absolutely essential if new therapeutic techniques are to be made available to patients without undue delay.

However, there is no doubt that a need also exists for this same Extraordinary Treatment Committee to eliminate those ineffective medical practices or effectual psychotherapeutic techniques still considered to be "accepted and routine practices of medicine" in some communities. Despite all of the available well-designed research studies that show the significant efficacy of antipsychotic compounds in schizophrenia, there are still some psychiatrists who use only psychotherapy in treating those schizophrenic patients, while keeping these patients institutionalized for long durations of time at great financial costs to the families. This type of current medical practice would have to be evaluated by the Extraordinary Treatment Committee. If this new legislation is to adequately protect the human subject (patient or research patient

or volunteer) in biomedical and behavioral research, Section 202 (a)(1) (B)(i) should be written as follows: "shall consider ... (i) The boundaries between biomedical or behavioral research involving human subjects and the competent practice of medicine based upon scientifically valid experimentation." As stated previously, those current medical treatment techniques that have not been validated by controlled scientific observations may be allowed to be continued on a temporary basis. However, governmental support of statistical evaluations and comparisons of the presently unproved techniques now utilized as "accepted and routine practice of medicine" should be immediately initiated. Thus, the government would fulfill its obligations to upgrade the standard of medical practice as well as to protect the human subject in biomedical and behavioral research.

Additional Examples for Caution in the Development and Interpretation of Guidelines

Since research in the field of psychopharmacology is much more extensive and more reliable than in the area of behavioral therapy or psychotherapy, I should like to refer to some problems of psychopharmacology (which is only another therapeutic tool in the treatment of mental illness) that the committee should be aware of in preparing its recommendations to the President, the Congress, and the Secretary. In the use of antipsychotic medications for schizophrenic patients, there are at least six major drug variables which determine the differences in dosage that patients require. In fact, these same drug dosage variables apply to

all oral medications ingested by all of us.

- 1) Each of us may react differently to a drug if the setting or environment is changed.
- 2) Each one of us has a unique interpersonal reaction to the person administering the drug which may affect our reaction to the medication.
- 3) The absorption rate of the drug may vary according to whether it is dispensed in capsule or tablet form.
- 4) Each one of us absorbs at a different rate from the gastrointestinal tract.
- 5) Each one of us metabolizes or "burns up" the drug at different rates as it passes through the liver.
- 6) The end-organ for which the drug is intended (in the case of schizophrenia, the brain) requires a different blood concentration in each individual.

Considering these six major variables that affect the response to drugs or medications, one can easily understand why one patient might require 5 times the dosage of Dilantin to stop his epileptic seizures as another patient, and some schizophrenics may require four or five-fold increases in maximal dosages of medication in order to show a therapeutic response. Thus, when the FDA approves a maximal recommended dosage, which is then printed in the Physician's Desk Reference, this current "accepted" standard guideline may hinder the competent physician who is knowledgeable in the area of pharmacodynamics, which considers the above major variables in drug metabolism. In the Wyatt case which has accomplished much

good, we also see a hinderance of the intelligent physician when we come to the court guidelines which utilize the Physician's Desk Reference for maximal dosage. A physician at one of the state hospitals in Alabama had to write to the judge responsible for the case as follows: "... the alternative to the constraints placed on adequate treatment of an individual using the FDA level requires a combination of several different drugs up to the prescribed levels in order to achieve the appropriate psychiatric treatment effects for the patient. The latter alternative, while somewhat effective, does raise a question as to the appropriateness of combining medications to achieve an effect of a single medication with a dosage that exceeds the FDA levels. Individual patients have different levels of tolerance to medications which makes almost every administration and dosage level an individualized one." Thus, this physician had been placed in a position of using what we call polypharmacy which is usually bad medical practice; this type of polypharmacy had been inadvertently caused by the guidelines set by the court. Thus, in getting guidelines to decrease the mistakes of the incompetent physician, the court unfortunately also hindered the knowledgeable physician from using this knowledge for the welfare of the patient. However, in the same case the court offered helpful guidelines for aversive conditioning which was designed to alter aggressive behavior. The court made the final recommendations that:

... no patient shall be subjected to any aversive conditioning or systematic attempts to alter his behavior by means of painful or noxious stimuli except under the following conditions: a) a program of aversive conditioning recommended by a Qualified Mental Health Professional trained and experienced in the use of aversive conditioning. This recommendation shall be made in writing with detailed clinical justification and explanation of which alternatives and treatments were considered and why they were rejected ...

b) any program with aversive therapy proposed for the benefit of institution patients shall have been reviewed and approved by that institution's Human Rights Committee before its use and shall be recommended by Qualified Mental Health Profession for an individual patient ... c) the patient has given his expressed and informed consent in writing to the administration of aversive conditioning ... d) no aversive conditioning shall be imposed on any patient without the prior approval of the Extraordinary Treatment Committee, formed in accordance with this paragraph, whose parent responsibility it is to determine, after appropriate inquiry and interview with the patient, whether the patient's consent to such therapy is, in fact, knowing, intelligent, and voluntary and whether the proposed treatment is in the best interest of the patient. The Extraordinary Treatment Committee shall consist of five members to be nominated by the Human Rights Committee of the hospital and appointed by Court. The members shall be so selected that the committee will be competent to deal with the medical, psychological, psychiatric, legal, social and ethical issues involved in such treatment methods; to this end, at least one member shall be a neurologist or specialist in internal medicine; at least one member shall be an attorney acting as the patient advocate and licensed to practice law in this state. No member shall be an officer, employee or agent of the Department of Mental Health; nor may any member be otherwise involved in the proposed treatment.

The court order goes on to state that "no patient shall be subjected to an aversive conditioning program which attempts to extinguish or alter socially appropriate behavior to develop new behavior patterns for the sole or primary purpose of institutional convenience." Thus, easy availability and accessibility of the ETC for the evaluation of the aversive conditioning technique would be of essential help in protecting the subject. If the aversive technique were based only upon empirical observations in other medical reports and not upon scientifically valid, controlled studies, it would then be the responsibility of the ETC to require that a controlled trial of the specific aversion technique be conducted, with the protocol approved by the local Institutional Review Board, before the technique is utilized as a standard or routine treatment procedure.

Further Explanation of the Recommendation to Change the Wording in Section 202 (a)(1)(B)(i)

I have previously suggested that the consideration for the NCPHSBBR should have been "the boundaries between biomedical or behavioral research involving human subjects and the competent practice of medicine based upon scientifically valid experimentation." The change in the wording has been recommended because it helps to differentiate clearly between research and what should be "the competent practice of medicine" rather than the "accepted and routine practice of medicine" which confuses the entire assignment given to the NCPHSBBR. Using this change in wording delineates research from the practice of medicine and defines the major difference. In addition, this wording may be utilized as a guideline that not only protects the research patient against the incompetent physician but may also be used to help develop and maintain competent treatment methods for patients; it may further serve to help the patient understand his particular role in relation to the physician who is treating him. There is a thin line in many cases between the use of therapeutic technique or drug for treatment and for institutional advantage. Again, the availability of the ETC will help to decide individual cases, using the guidelines as state above. Research is an exploration of a new technique or medication that has not yet been shown to have significant therapeutic efficacy as compared to a currently available medical practice or to an inert substance, and the risks of this technique or medication are relatively unknown. On the other hand, the "competent practice of medicine" should be based upon scientifically valid observations that have been detailed in the medical literature.

It should be remembered, however, that a physician is not bound to use one specific therapeutic method or drug for a particular disease. The physician has the opportunity and the responsibility to select from among all generally accepted modes of therapy as long as there is a scientific, logical basis for the determination. Moreover, the physician cannot guarantee a cure, but only the exercise of his skill, experience, and best judgement for the particular patient. It would be unfortunate if rules to insure rights and benefits became impediments to personal care and individualized therapy. However, accountability is needed and is proper within the contexts of both research and medical practice by even the most conscientious physicians. At the same time, too many detailed constrictions based on inadequate scientific evidence would tend to move most therapeutic techniques or approaches toward the average or the mediocre or toward the "accepted and routine practice of medicine" which is not always acceptable at the present time.

Proposed Guidelines for the "Competent and Routine Practice of Medicine"

"Competent and accepted routine practice of medicine" should utilize medical techniques which have been validated by scientific experimentation. In addition, the proper and accepted routine practice of medicine should include the following information before initiating treatment: 1) diagnosis, symptom profile, and etiology of the disease; 2) course and history of the disease; 3) treatment of choice; 4) anticipated beneficial effects and side effects of the treatment technique; 5) alternative treatment techniques available for the disease; 6) the physician should

should be knowledgeable about the scientific research results concerning the treatment techniques that he is applying to the patient and should fully inform the patient about the important aspects concerning the side effects as well as beneficial effects of the treatment technique; 7) the physician should have some concept of the duration of treatment and this aspect should also be explained to the patient; and 8) the patient should be informed about what alternative treatments are available, if any, if the present treatment technique fails or progresses too slowly.

Concluding Remarks

Biomedical or behavioral research involving human subjects has been defined as well-designed and critical investigations of a therapeutic technique with unknown efficacy and risks or an attempt to find the etiology of a disease having for its aim, the discovery of new facts or the revision of the present techniques associated with the "accepted and routine practice of medicine" with the ultimate goal of providing beneficial effects for human subjects. The latter part of the sentence in Section 202(a)(1)(B)(i) which is worded, "the accepted and routine practice of medicine" has been changed in this paper to read, "the competent practice of medicine that has been validated by scientifically valid experimentation." Human research shall not include those studies which exclusively utilize tissue or fluids or other products after their removal or withdrawal from a non-pregnant human being. In this manner, an attempt has been made to delineate more clearly the proper practice of medicine from the proper conduct of research. The author considers "the accepted

and routine practice of medicine" in this country as well as in many other countries to be unacceptable in certain situations, and there are many physicians whose performance does not always meet reasonable criteria of quality. The physician in charge of treatment of the patient should be using a treatment modality which has been shown in scientific experiments to have been more efficacious for the specific disease than comparatively inert treatment techniques or substances. In addition, the physician should have a reasonable expectation that the treatment imposed on patients who have a questionable understanding of informed consent (thus, their legally authorized representative signs consent) will produce changes that the patient would seek if he were more rational. Any question of the efficacy of the treatment technique or treatment goals should be reviewed by the Extraordinary Treatment Committee (ETC). In those psychiatric emergencies concerned with patients presenting acutely suicidal or homicidal behavior, treatment may be immediately instituted on admission of the patient to the hospital, but any question of the efficacy of the treatment technique or treatment goals should be reviewed by the Extraordinary Treatment Committee within a reasonable period of time after treatment has been initiated. It should be emphasized that the undue delay of treatment may be harmful for the long-term as well as short-term prognosis of the patient. Therefore, if the Extraordinary Treatment Committee system is to function for the welfare of the patient, several of the key members of the ETC will have to be full-time administrative staff members who are not employees of the institution or clinic where the patient is undergoing treatment. Extraordinary Treatment Committees should be available for out-patient community facilities as well

as for institutions. If any treatment technique should lead to serious questions as to its safety or efficacy, evidence from the published scientific literature and from the clinical experience of qualified experts should receive substantially greater weight than what is considered to be the "accepted and routine practice of medicine" which frequently is below the standard that we expect in this country. If the question is related to drug use, then the evidence from the scientific literature and clinical experience of qualified experts should receive substantially greater weight than the statements printed in the package insert and Physicians Desk Reference (PDR).

I have referred to Dr. R. Levine's July 14, 1975 paper several times and would like to state that I would agree with him on most of the major points that he raises in his manuscript if the "accepted and routine practice of medicine" were adequate. His conceptual models on page 5 would be valid if "routine and standard practice of medicine" were deemed to be adequate. However, the proper and competent practice of medicine should be based upon scientifically validated experimentation or on empirical knowledge that the presently used mode of treatment is the best available technique for the specific disease at this time. In many cases, there is no doubt that one can differentiate the intent of the professional researcher from the practicing physician. However, it is my opinion that there are many exceptions to this observation and that in many cases it would be impossible to differentiate the innovative and intelligent physician who is using a standard medication with a slightly different approach for the benefit of the patient from the researcher who is attempting to gain new knowledge from the use of the same medication.

Similarly, in some situations it may be very difficult to differentiate the intent of the incompetent physician who is using "a standard type of treatment" in an inappropriate manner from the incompetent research person who is performing an ill-designed project in an uninformed patient. These are some of the reasons why I reworded Section 202 in my attempt to delineate research from what should be the "competent" practice of medicine. I strongly agree with Dr. Levine's statement on page 14 that some physicians may "proceed with pure practice intent" with an innovative therapeutic approach after other treatment modalities have failed. However, according to the definition in this manuscript and according to the present regulations, these intelligent, innovative approaches are still considered to be research. Thus, I once again must re-emphasize the essential need for an Extraordinary Treatment Committee easily accessible for a rapid evaluation of this type of innovative treatment approach, thus eliminating a great deal of bureaucratic paper work for this particular type of practicing physician. Otherwise, under present regulations, he would be forced not only to write out a detailed research protocol but to have it evaluated by an Institutional Review Board which may only meet once monthly. This delay of treatment could be disastrous for the patient. Thus, the patient would be the main individual to suffer under the present system when he has the good fortune to be treated by an intelligent, innovative physician.

It has been previously mentioned in this paper that there are many people practicing behavioral therapy, psychotherapy, marital counselling, encounter therapy, etc, who do not require licensure by the state in which they reside, have not received adequate training, and are not

subject to any legal controls. This situation is ridiculous and must be addressed by the NCPHSBBR since these individuals are frequently utilizing treatment techniques that are not scientifically grounded and are not based upon any scientifically valid experimentation. Thus, these individuals are actually performing behavioral research with human subjects without any restrictions or controls or guidelines. The requirement that such individuals be evaluated by an Extraordinary Treatment Committee may prove to be of great benefit to a major part of the patient population which is now being treated by these individuals. There is no doubt that the patient population treated by these unproved techniques and unqualified personnel are within the subject population that the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has to report about to the President, the Congress, and the Secretary.

It is apparent that the cost of treatment for mental health will increase even more if the Extraordinary Treatment Committees are to be effective committees with full-time administrative staff and not just rubber stamp committees. However, the possible elimination of ineffective and expensive treatments such as psychosurgery and psychoanalysis for schizophrenic patients (See P.R.A.: Treatment of Schizophrenia: A Comparative Study of Five Treatment Methods, Science House, New York, 1968) may partially or completely compensate for the additional costs. Although it is recognized that it would be impossible for the Extraordinary Treatment Committees to review or even be aware of all treatment and research problems, the very existence of these committees would serve as a deterrent for the negligent therapist or researcher and would

foster a more cautious, thoughtful attitude in all who are involved in research or treatment.

ON THE USEFULNESS OF INTENT FOR DISTINGUISHING BETWEEN RESEARCH AND
PRACTICE, AND ITS REPLACEMENT BY SOCIAL CONTINGENCY:
• IMPLICATIONS FOR STANDARD AND INNOVATIVE PROCEDURES,
COERCION AND INFORMED CONSENT, AND FIDUCIARY
AND CONTRACTUAL RELATIONS

Israel Goldiamond, Ph.D.

Advances in biomedical and behavioral research have aroused public concern in at least two areas. These are the social implications of the advances and the human means necessary to produce them. The present discussion centers on the latter, specifically as it relates to human experimental subjects undergoing experimentation and human patients undergoing treatment. In both cases, there is professional manipulation of outcomes, which can contribute to advances. Nevertheless, a commission has been established to consider the protection of subjects, rather than patients, or than both.

If there are distinctions between the two areas, as is implied by the Commission's mandate, then there are at least three reasons to make them explicit. First, such distinction is necessary if the scope of deliberation by the Commission is to be defined. Second, such distinction will tend to curtail expansion into one area of controls properly directed at the other. In legislative terms, in the absence of clear distinctions, rulings directed specifically at, say, experimentation, may come to be extended to treatment, and rulings which specifically exclude treatment may come to exclude experimentation. Third, if meaningful distinction is not possible, there may be repercussions far beyond these, given the present social climate. Reports of abuse of human subjects have occasioned the present scrutiny of the means for such abuse, which adhere to experimentation. If treatment is indistinguishable from experimentation, then the same means for abuse are also inherent in treatment. Accordingly, whatever social winds sweep at experimentation will also sweep at treatment. Indeed, Senate hearings (Hearings before the Subcommittee on Health, 1973) on S. 974, training in "implications of advances in biomedical research and technology;" on S.J. Res. 71, evaluation of implications of such advances; and S. 878, "provision of restrictions on funds for experimental use" are

published under the title Quality of Health Care -- Human Experimentation 1973. In addition to not being immune from incorporation into the questioning of research, the routine and accepted practice of medicine is becoming routinely less accepted on its own, as suggested by the rising cost of malpractice insurance and the increasing scrutiny represented by books such as The End of Medicine (Carlson, 1973).

That the distinction between practice and research is not self-evident derives in part from the fact that research is often performed in the context of treatment: the person who is a patient may at the same time be a subject in a biomedical or behavioral experiment. Indeed, much of the research upon which advances in treatment often depend can be conducted only under such circumstances. Even when practice and research are separated, it seems to be generally accepted by reviewers that treatment is often indistinguishable from experimentation. Thus, Beecher states that "whenever the physician tries out a new drug or a new technique... he is experimenting in his effort to relieve or cure the individual involved" (1970, p.83) but this is extended to "every medical procedure, no matter how simple or accepted," by Ladimer. Treatment "is an experiment since it is applied in a new context each time" (1963, p. 190). F. Moore expands this into several experiments in the course of one treatment episode: "Every surgical operation is an experiment in bacteriology," he states, and is simultaneously an experiment "in the pharmacology of anesthetic drugs ... in the conformity to anatomical norms, and often in the biology of malignant tumors" (1975, p. 15). Levine's overview is indeed apt: "Even a superficial exploration ... will reveal the impossibility of describing mutually exclusive subsets (one called research and one called practice)" (1975a, p. 1).

In both cases, manipulations derive from systematic approaches; the intervention procedures used and the results obtained are recorded; these are evaluated in terms of baselines, basal measures, or other norms; the interventions are subject to change depending on their outcomes. Other similarities exist. Given the social importance of distinguishing the two subsets, and given the overlap between observable behaviors, the use of a subjective unobservable to distinguish the two is understandable. The history of psychology is replete with the introduction of such terms to distinguish between processes which it is important to separate, but which the verbal-observational system in use does not permit. (As will be noted, the history of psychology also reports correctives.) In this case, the "taxonomic" function is assigned to intent. Thus, regardless of overlap between procedures described, they are classified as treatment where there is "therapeutic intent," and as experimentation when the professional's "motive is indirect benefit to society, not benefit to the patient" (Blumgart, 1969, p. 252). And this holds even if the patient benefits thereby; conversely, if the professional "believes (even if only on the basis of advertising) that [the treatment] will do the patient good, then he is acting as a physician," presumably even if it does him no good (Edsall, 1969, p. 466). The general opinion is summarized by Levine: "If a physician proceeds in his interaction with a patient to bring what he considers to be the best available techniques and technology to bear on the problems of that patient with the intent of doing the most possible good for that patient, this may be considered the pure practice of medicine." (1975a p. 6). He reports a second system of classification, namely, group acceptance or approval, presumably of a particular procedure as treatment. The two systems can conflict, as when a physician uses a new drug with the intent to doing the most possible good for the patient, while this drug

has not yet been approved for "safe use" in such cases by a procedure-accrediting group -- here, the Food and Drug Administration (1975a, p. 11). Intent would then be overridden. In such situations, research would be defined by efforts deriving from an intent to distinguish between classes of patients for whom a treatment should be approved or disapproved, since the intent is to provide generally useful information. Treatment would be restricted to the use of the procedure, when approved, with the intent of doing the most possible good for a particular patient.

Undoubtedly, there are differences in intent when research or treatment is undertaken, and subjects and patients do have different expectations. While these differences may be along the lines noted, it would seem that intent is a rather slender reed upon which to build public policy, especially where issues as important as those noted rest upon this platform. That intent is used in its subjective sense is made clear by Levine's quotations from the dictionary, e.g., "the state of mind or mental attitude with which an act is done" (1975b, p. 2a). The question arises of how one ascertains intent or, more properly, ascertains individuals' "state of mind or mental attitude" in the performance of their acts, or in their "concentra[tion] on some end or purpose" (ibid). The definition of someone's intent through consensus by experts is no more valid than such assignment by a single person and, ever since Freud, at least, we have learned to question even self-assignment of intent, no matter how sincerely or tenaciously held.

Subjective terms such as intent, expectation, desire, motive cluster around a common core close to the subjective dictionary definition noted. They may be used in several ways, among which are the following. (1) Subjective: The terms are used with reference to this common cluster. Specifically, research and treatment are distinguished by differences in intent and

expectations (Ladimer, 1963, p. 192). This usage imposes the validation difficulty noted, with its attendant problems for social policy. (2) Indicator: The subjective terms may be considered as indicated by clearly stated relations between explicit sets of procedures, called indicators. The indicators do not define the subjective processes, which are independent of them. Specifically, the different monetary exchanges in research (professional pays subject) and treatment (patient pays professional) stem from differences in intent; they may indicate the existence of such differences but do not define them (Levine, 1975b, p. 8a). Although the indicators may be readily defined, the validation difficulty of the referent remains, as do the social consequences noted. (3) Operational: Terms with an originally subjective meaning may be used as a metaphor or simply as a convenient label for clearly stated relations between explicit sets of procedures, which define the terms. Specifically, research intent is defined by certain stipulated procedures, and treatment intent by yet others. The terms have no other properties. This is the most familiar form of the operational definition. It couples clarity and ready validation with what is often the exclusion of the area of concern. (4) Operant contingency: The social importance attached to subjective distinctions may be considered as representing important differences in social and personal consequences which are contingent on the behaviors which are occasioned by the systems discussed. Specifically, if differences in intent are consistently used to separate research and treatment, this may derive from important differences in the social and personal consequences contingent on behavior in the two institutions.

Overlap between many of the behaviors in the systems necessitates the introduction of a classification system other than behavior. This can be

intent which, unfortunately, leads to validation problems, since it is unobservable. However, the alternative classification system can also be the operant (as opposed to operational, cf., J. Moore, 1975) contingency, which does not define terms simply by the behaviors, but also by their relation to the consequences differently contingent on them in the two settings. These, too, are observable and can be validated. They fulfill the same logical necessity to which subjective intent is addressed, and may serve the same social functions. The system of analysis, however, is not as familiar as the others, nor has it been used as extensively in discussions of social issues. Accordingly, it can not be referred to as readily, nor stated as simply. The simplest statement, of course, is intent. However, the complexities and difficulties encountered when one tries to apply it meaningfully to matters of social policy suggest that the verbal simplicity provides little help in systematizing the issues to which it is addressed. This drawback is also encountered in subjective definitions of consent (i.e., did the person really understand?) and the coercion which jeopardizes its legal acceptance.

This discussion is addressed to the problem of making explicit the social and personal contingencies to which terms such as intent, coercion, and consent are addressed, in the context of distinguishing research from treatment and, therefore, of distinguishing human subjects of biomedical and behavioral research from human patients of biomedical and behavioral treatment. In the process, I shall note ancillary issues such as the different types of contractual relations involved, as well as some assumptions on which these are based.

The discussion will open with a brief exposition of the analytic system, its commonalities with cognate systems in the social sciences and in law. I shall examine a legal use of intent as a taxonomic device to apply differential treatments, for the clues it contributes to this discussion.

I. SOCIAL CONTINGENCIES AND LEGAL INTENT

The opening discussion of operant contingencies will be confined to that which is necessary for the later presentation.

The "three-term" formulation of an operant contingency requires that at least the following elements be specified: (1) the occasions upon which (2) consequences are contingent (3) on behavior (cf. Skinner, 1969, p. 7). The term contingency refers to the fact that unless the behaviors occur, the consequences will not follow. Another way of stating this is that the behavior is required (if the consequence is to occur) or is a requirement (for its occurrence). The consequence, however, need not follow every behavior occurrence: a fixed or variable number of responses, or a period of no behavior may be required, among others. The event in (1) may be said to occasion the behavior or provide the opportunity for it. Presented in order of appearance, the contingency is described as (1) occasion, (2) behavior, (3) consequence.

Where, given the occasion-behavior-consequence contingency, the behavior increases in likelihood when the appropriate occasion occurs, a reinforcement contingency is defined. In positive reinforcement, the behavior-increasing consequence is the presentation of an event. In negative reinforcement, the behavior-increasing consequence is the postponement (avoidance) or elimination of an event (escape). Given occasion-behavior-consequence relations, and the behavior decreases in likelihood, a punishment contingency is defined. Punishment can involve postponement or elimination of an event (typically, one whose presentation is positively reinforcing), or it can involve presentation of an event (typically the events whose withdrawal is negatively reinforcing).

It will be noted that whether the contingency is defined as reinforcement or as punishment depends on whether or not behavior was increased or

attenuated, respectively, and not upon the intent of the wielder. A parent who intends to stop a child's annoying behavior or to prevent its recurrence, and behaves in a manner judged by self and others to be punitive, will be defined as having instituted a reinforcement contingency -- if there was an ensuing increase in behavior. If the behavior did indeed cease, this outcome might then reinforce the parent's punitive behavior on those occasions when the child misbehaves. Being punitive is the requirement for obtaining relief.

One last point will be made. Whether or not presentation of a consequence will affect behavior will depend on antecedent conditions which must be specified. Whether food can reinforce behavior depends on the organism's degree of deprivation, upon the cultural definition of that food as permissible or forbidden, among others. Further, events may acquire reinforcing or punitive properties through their relation to other events. Where the behavior required for reinforcement is an extended sequence of interactions with the environment, each component link in that chain may be considered as an occasion-behavior-consequence link. This consequence derives its reinforcing property from its progressive relation to that consequence for which the whole sequence is required.

The formulations may be used to analyze social relations, and the procedures developed may be used to change them. When one person is engaged in extended interaction with another or with a system, the behaviors of each may be viewed as occasions and consequences which bracket the behaviors of the other. Each consequence may derive its reinforcing properties from its relation to a consequence at the end of the chain-requirement, or for other reasons.

The relation can be considered in terms of gains for each. The advantage can be considered positive, e.g., obtaining something valued, or negative, e.g., obtaining relief from distress. The relationship can be

described in terms borrowed from the market-place: there are transactions involved, with one person's behavior providing the other with something valued, and the other providing something valued in return. In its original usage (before its corruption by psychotherapists), transactional analysis referred to such relationships, often involving extended verbal intercourse. The descriptive metaphor may be a barter system, with exchange theory being the model. Decision theory may be viewed as a related development. A decision requires at least two well-defined sets of behavior, which intersect with at least two states of the environment. A 2 x 2 matrix is thereby defined, with the entry in each being the consequence of that behavior under the particular environmental occasion. All four consequences must be considered, in accord with some decision rule, and the analysis often consists of ascertaining which decision rule rationalizes the empirical data obtained, that is, which provides the best fit. It will be noted that where the states of the environment, present or future, are unknown, there is risk attached to either behavior, since the consequence may or may not be a gain, depending on state of the environment. Cost-benefit analysis also considers the consequences which are contingent on behavior, but in contrast to the decision model presented, in which either of two consequences is contingent on behavior (depending on the occasion), in cost-benefit analysis, at least two consequences are often both attached to the same behavior.

Each of these models covers overlapping terrain, and also considers variables not considered by the others. Differences in metaphors, that is, the languages they use and the concepts they relate these to, as well as differences in variables considered derive from the different requirements of the academic disciplines, e.g., transactional analysis in anthropology, exchange analysis in sociology, decision theory in economics, and operant contingency analysis in the conditioning laboratory, from whose requirements

much of the terminology and procedures derive. Differences in terminology and metaphors have tended to restrict communication between models. Where a model has been applied to a discipline other than its origin, it has often led to bursts of progress (e.g., decision theory applied to perception and clinical decisions), since it contributes procedures which are new to the adopting discipline. Although the language has often been subjective, e.g., participants have expectations, they make decisions, they hope or intend to optimize net gain, what makes the adoption useful is the procedures for analysis it provides. I shall consider the relevance of such procedural analysis for analysis of legal intent.

It would be surprising if the legal system, faced with decisions which have social consequences, had not come up with similar procedures. Where power over life, liberty, and property is involved, the consequences of definitions in terms which are open to a variety of interpretations in practice, and in terms which are quite specific and limited, can be markedly different. For example, Currie (1968) attributes differences in the number of witches executed in Renaissance Europe on the Continent (500,000 estimated executions) and in England (less than 200) to differences in the stringency of the definitions of witchcraft applied by the different legal systems, and to the different consequences of conviction to the accusing system. Intent, as noted, is a difficult term to define. I shall consider its legal use in mens rea, or criminal intent, specifically with regard to intent to commit murder.

Wexler, a legal scholar, notes that "the law is ripe for contingency analysis" (1975, p. 174) and that such analysis "can help to clarify the definitional and evidentiary aspects of hazy and imprecise legal concepts" (p. 175). He also notes that previous attempts "to purge the penal law of the concept of mens rea ('criminal intent') ran head-on into

numerous obstacles and objections" (p. 175). However, as was discussed, there is a difference between the operational definitions associated with classical behaviorism and the operant contingency definitions associated with radical behaviorism (Skinner, 1974).

Two types of contingencies will be noted which are related to the statement that someone "did willfully and knowingly intend" to commit murder and then carried out his intent. The first contingency to be discussed defines the intent which distinguishes first degree murder. The second defines the social consequences contingent on differentiation of murder by intent and other types of killing.

1. Intent defined. Three things are involved here: motive, opportunity, and means.

Motive is defined by the consequences of the act. A victim is found dead in Trenton with a bullet hole through his head. If it turns out that a nephew is bequeathed \$50 million as a result, the nephew is considered as having a motive. The French maxim, "Cherchez la femme" suggests a prevailing consequence (motive) in that society.

Opportunity. This is where the alibi enters. If the nephew was in San Francisco at the time, he may not be as likely a suspect as if he had been in Trenton, in the neighborhood of the crime, at the time. He will then be a suspect.

Means. The nephew has recently purchased a carbine, has practiced, and the murder bullet was .30 caliber; the nephew reports that the rifle had been stolen the week before.

The nephew is the prime target, and the state will make every effort to demonstrate that the means was probable behavior. He may be indicted and, despite his strenuous denials, a jury of his peers may find him guilty of murder with intent, that is, first degree murder.

It will be noted that the three-way operant contingency discussed earlier is considered to be present: opportunity, consequence, behavior. Intent is thereby defined.

2. Social necessity. If the uncle is killed in what appears to be a traffic accident, and the driver had no motive, the law will treat this differently. If, in addition, the driver had exceeded the speed-limit, the law will treat this yet differently. If, in addition, the driver was fleeing the scene of a robbery he had committed, this will be considered the equivalent of first degree murder. To the immediate family, the results are operationally the same: they have lost a beloved member of the family. He is just as dead in each case, including the murder case. The law will not bring him back, yet it treats the killings differently.

On (a) the occasions of the offenses cited (b) the consequences for society (c) of classifying the offenses in actionable categories must be considered in accord with a particular social policy. Inspection of the offenses, classes established, and social consequences suggests what the policy may be. With regard to the intent-to-kill contingency discussed, societies apparently abound with people whose elimination would be useful to other people. Societies also abound with earnings which may be obtained by theft and other felonious behaviors. Both the temptations and behaviors which yield to them are prevalent. In addition, the behaviors are amenable to social control. Accordingly, the law intervenes to decrease the likelihood of these behaviors by threatening its most drastic punishment, and applies the general term "first degree" killing. However, to paraphrase La Place's maxim on the improbable, accidents allow themselves the luxury of occurring. No legal sanctions can prevent them from occurring, so the law will not apply its deterrent. A component of social policy may be inferred from the discussion, namely, that severity of consequence be

directly proportional to its efficacy in decreasing the likelihood of the offense. The more effective the punishment on behavior, the more severe it should be. Another component of social policy may be inferred from the different punishments attached to killing when the speed limit was exceeded or when a felony was committed. Both speeding and felonies may be amenable to control by social deterrents, but the offenses differ in a variety of ways, including prevalence, and the likelihood of general damage to the social fabric. The presence of yet a different component is suggested by lex talionis (e.g., a life for a life), whereby the severity of the legal consequence is governed by the general severity of the offense. Here, all types of killing might be treated similarly.

No pretense is made that the discussion is exhaustive; the writer is a legal layman. Nevertheless, the two contingencies presented suggest that legal resolution, although often couched in subjective terms such as intent (coercion and consent will be considered later), is amenable to contingency analysis and possibly was formulated in accord. It was noted earlier that various social disciplines have almost independently developed forms of contingency analysis and there is no reason to assume that this is not the case for law. It is of interest that decision theory, a system of complex contingency analyses, employs, as does the law, subjective metaphors to label its components, e.g., a decision is made, a strategy is followed, it may be governed by its expectations. The terms, however, are names for explicit procedures and explicit formal (mathematical) relations between procedures and data. The bases for classification are the observables and their relations, and not the subjective designations given them, nor, for that matter the dictionary definitions of the designations.

Nor should it be assumed that the contingencies presented are those which actually occur. Only a careful fine-grain analysis of the actual workings of each system can indicate what contingencies are actually operating

in that system, as opposed to those which "should be," as defined ethically or as stipulated by its empowering group or by its own members. The contingencies presented are purely heuristic, and serve to suggest some necessary considerations for social definition.

Contingencies of classification of social activity.

Assuming that contingencies are employed in classification (if human behavior is under consideration, since it is sensitive to influence by consequences, such contingency analysis is suggested), the discussion suggests that at least two social contingencies are required. One is the particular contingency which defines the class to be treated. The other contingency governs the specification of a classificatory scheme, whereby the first contingency is distinguished from others in the scheme.

A variety of classificatory schemes can be proposed, each of which can be stated as a contingency. The social policy which affects the choice of one rather than the other should be made explicit. A parallel is found in decision theory where, for the same sets of contingencies, different decision criteria or decision goals, are offered (e.g., minimax, maximin, Neyman-Pearson criteria) which set different types of outcomes as acceptable, and thereby require different policies, or strategies of choices.

Decision theory may be employed normatively, that is, to suggest strategies which accord with the policy, e.g., if average losses are to be kept below a certain level (minimax), a specified strategy should be followed.

Decision theory may also be employed descriptively. For the actual choices and their consequences, the question may be raised as to which decision criterion best rationalizes the data, that is, which best fits the data. This postdiction may then be validated by prediction of experimental or other research outcomes. It should be noted that it is not necessary to assume that the choices were governed by rational intent. Animals have

been excellent subjects for decision research. The decision criterion which rationalizes the data is the one which makes the most sense to the analyst, not the "decision maker".

Finally, a discrepancy between socially normative criteria and descriptively inferred criteria may be used to orient programs of change. Indeed, as Gray (1975) concludes, "relatively little consideration has been given to mechanisms or procedures that might help assure that the ideals are achieved" (p. 245). He notes that an institution may set up peer review committees only because consequences such as protection of the institution and a continued flow of research funds are contingent on such behavior. Further, the very review procedures chosen may be those whose consequences are simply to "appear to meet the official goal" (1975, p. 46, original emphasis).

Decision theory specifies its requirements, procedures, and outcomes in explicit terms which are related mathematically and are often so defined. Obviously, all of these can not be met -- what quantity do we assign a human right or an iatrogenic dysfunction (even if a jury does)? Nevertheless, it may be worthwhile to specify those classes of observations and relations which the theory requires, and consider them explicitly, for policy formulation.

Contingency analysis, as used in decision theory and in operant behavior analysis, would appear to be useful in consideration of social issues and policy. We shall now consider such definitions of treatment and research.

II. TREATMENT AND RESEARCH

The first two terms of the three-term contingency which specifically define treatment and research will be considered together since (a) the occasions and (b) the consequences (which will then be contingent on behavior) are defined in terms of each other in a manner to be noted. The third element, (c) the behaviors then required, will be considered separately. The different contingencies for patients and subjects and for their corresponding

professionals will be noted in a separate section which will also consider the means-ends differences often assumed to distinguish patients from subjects.

Discussion of the social contingencies and policy which specify a particular classificatory scheme will be dispersed throughout and accordingly will not be restricted to a separate section.

Occasions and consequences in the social definitions of treatment and research.

There are interesting parallels between the occasion-consequences relations of the treatment and research systems. These parallels are along lines other than patients and subjects.

In the various treatment systems, the events which occasion treatment are individuals (collectives may be considered as such) who present functioning which is less than adequate or which poses problems, and the consequences which maintain treatment are progress toward, and it is hoped, production of functioning which is more adequate than before, for the same individuals. The individual units can be humans who are designated as patients going through a clinical system, as students through an educational system, as trainees through a training system, and so on. The units can be animals going through clinical or training systems. The units can also be automobiles or electrical appliances going through their repair systems. The transmutations in functioning may be designated in terms such as correction, enhancement, innovation, limitation, repair, restoration, and treatment, among others.

In the various research systems, the events which occasion research are somewhat systematized and organized statements or related problems, and the consequences which maintain research are progress toward and, it is hoped, better organized statements. The criteria used to evaluate the organization include, among other things, changes in consistency, parsimony, coverage and, for those empirical systems we call scientific, validation by prediction or control. The transmutations along these lines may, like treatment,

be designated as correction, enhancement (extension), innovation, limitation, repair, restoration, and treatment, among others.

The changes attributed to the two systems may be described as the positive reinforcers of functioning, healthy, or educated individuals in the treatment systems and of better-systematized statements or new knowledge in the research systems. The changes attributed to the two systems may also be described as the negative reinforcers of relief from distress or ignorance. Although these consequences whether viewed "constructionally" or "pathologically" (Goldiamond, 1974) are not always produced by the social institutions (n.b., school ineffectiveness), they are considered to be contingent upon their proper functioning, and the consequences (no matter how variable) therefore maintain social support of the institutions. The support can be financial, as in research, or partly financial and partly also in the granting of virtual state monopoly, as in the school systems and medical licensing systems.

This cursory analysis suggests that in the clinical treatment enterprise and in the biomedical-behavioral research enterprise, the patient and the systematic formulation ("Nature") are analogous. The human patient and the human research subject are not analogous in considerations of the two enterprises as enterprises.

Behaviors in the contingencies defining treatment and research.

Whereas the differences between occasion-consequences in treatment, and occasions-consequences, in research seem clear, there is considerable confusion in the literature on differences between the third terms of the contingency, namely, behavior. As was noted in the introduction, "every medical procedure, no matter how simple or accepted" is considered to be "an experiment since it is applied in a new context each time" (Ladimer, 1963, p. 190). Since the outcome is never certain, "all or nearly all therapy is

experimental" in this sense (Beecher, 1970, p. 94; cf. Freund, 1969, p. viii).

Where there is uncertainty of outcome, the effort must be considered as a trial or as an attempt whose outcome is to be related to the trial to produce a type of knowledge or inference which is never certain, is fallible, and is therefore subject to change. When one contrasts the certainty of the a priori knowledge which derives from faith, the classical distinction between the a posteriori knowledge derived from experience and that derived from faith is evident. Indeed, the French word for experiment is expérience, defined in my Larousse Petit dictionnaire (1936) as "n.f. Essai, épreuve. Connaissance acquise par la pratique, par l'observation" as distinguished from knowledge gained through faith. Its specific meaning is "Particul. Essais, opérations pour démontrer ou vérifier une chose." The same term catches the common tentative quality of what English separates as experience and experiment. Indeed, to experiment is given by "expérimenter, v. tr. Eprouver par des expériences." The terms were not always separated in English. The OED reports that in 1382, Wyclif's translation of Genesis xiii, 15 (Revised Standard Version, 1952, "By this you shall be tested") opens "Now y schal take experyment of 3ou", but in the 1388 edition, it is "Now y schal take experience of 3ou."

Indeed, if this close linkage makes experiments of all experiences (both are derived from L. experiri. to try) then not only does all medical treatment become biomedical experimentation, as we are told, but all sensory experience and knowledge gained thereby becomes experimental. Possibly, this is what Moore was leading up to when he noted that "every surgical operation is an experiment in bacteriology, .. [in] pharmacology, ... [in] anatom[y], [in] bio[log]y" (F. Moore, 1975, 15), for shortly thereafter he speaks of "this basic experimental nature of clinical medicine and, indeed, of all human intercourse" (p. 16, emphasis added). Since teaching "is applied

in a new context each time," as is serving customers, and conversing, these, too, become experimentation with human beings.

A simple test which distinguishes scientific experimentation from the practices of clinical medicine, routine or innovative, of teaching etc., would be to apply the principle of concordance, in the form of a simple question: Would a group such as the National Science Foundation give research grants in bacteriology, pharmacology, anatomy, and biology for "every surgical operation", for every classroom session, and so on? If the distinction between the scientific usage of experimental and the lay (and professional usage by writers in the field we are discussing) usage of the term, and the distinction between experimentation and treatment are not clear to any investigator or practitioner who submits a research proposal, they will be clear after review.

What defines research varies with the discipline, the research strategy, the review agency or journal, and no definition will therefore be offered here. The peer review committees of the various granting agencies and the editorial reviewers of scientific journals and agendas of scientific meetings offer sufficient definition. Whether or not a particular project is proposed for such review, its designation as a research project might depend on an affirmative answer to the concordance question, which in this case is put hypothetically, and only to define the behavior.

Whether activity qualifies as acceptable treatment might similarly be defined by peer review, in this case weighted toward post-hoc review. If scientific review is to be used as an example, "track-records" of each practitioner might serve evaluative functions, just as department heads file publications of faculty for consideration of tenure and promotion, and just as grant review committees require such listings and evaluation of quality.

Where committees are institutional, its members are subject to the same contingencies which govern the person under review. Independence is preferable. To assert that the public is best protected by having reviewers who are outside the specialty and are therefore personally impartial misses the point. The critical issue is to ensure independence of contingency control. In areas where specialized knowledge is required it becomes all the more important to build in independent contingencies since the special interest groups being regulated are the ones which possess the special knowledge needed to regulate. Indeed, the history of governmental regulatory agencies shows that they wind up being run by the groups they are supposed to regulate. It should not be assumed that research and treatment will be exceptions. Even where the contingencies governing regulator and regulated are separated, there can be "deferred bribes", that is, hiring by the regulated once the term of the regulator is up.

The existence of yet a different type of public protection is implied by statements such as "doctors (or other professionals) always stick together." Where the implied consequence of a coverup of a person or agency is protection of a profession or other specialty group, the argument that only such specialists have the evaluative skills may be beside the point. The solution in practice is to have a review group comprising members of other specialty groups. However, this solution of professional impartiality may also miss the point, which is to ensure independence of contingency control.

For research in the context of treatment, if the research is to be meaningful it should meet the concordance criterion mentioned. If the treatment is to be considered acceptable, it should meet the criteria for treatment. Stated otherwise, clinical research should meet both criteria.

The concordance solution may also apply to a practitioner who, having provided acceptable treatment for some time, would now like to go over the

records for their possible contributions to science or general treatment. It should be noted that research grants are made for historical and archival analysis, and the research concordance principle would apply to the procedures for analysis, the records available, and so on. If types of patients (students, etc) and types of treatments selected allow comparisons and facilitate research, the use of intent as a taxonomic device poses a problem, since it may be inferred that choices for treatment were governed by the "intent of developing new knowledge" (Levine, 1975a, p. 6), that is, of research. The procedures are, after all, in concordance with research. If the treatment provided was concordant with treatment, it also meets this test. Selection of patients and treatments is also concordant with treatment, as evident by professional specializations in both patients and treatments; economic and other selection criteria ("I can't treat that type") abound. Using a particular type of procedure for a particular type of patient is, after all, what diagnosis is about. And if the particular patient-treatment interactions are treatment-concordant, the fact that they are also research-concordant may be the concern of the research review committee.

In all events, now that treatment is coming under public scrutiny, treatment systems might profitably examine the procedures developed by cognate systems governed by similar contingencies, namely, scientific research systems whose major funding has come from the same public sources that will be increasingly tapped for treatment, with the same requirements for accountability.

Effects on innovation and the accepted practice of medicine

The fact that innovative treatments or treatments in new contexts are defined as experimental (cf. Beecher, 1970; Freund, 1969; Ladimer, 1963;

McDermott, 1975; F.D. Moore, 1975) is of concern to lexicographers and will not be pursued further here. New procedures and new conditions can be concordant with treatment and, when so used, Freund sees "no quarrel" (1969, p. 317). Our concern will be with the testing of innovative treatments, which may fit the research contingency noted, although review committees tend to regard such proposals as "demonstration proposals" rather than "research proposals". Since innovation may be defined as a departure from "the routine and accepted practice of medicine", henceforth to be abbreviated raapo medicine, we shall also discuss raapo medicine when implications of innovation apply here as well. Research and treatment contexts will be treated separately.

If innovations are not to be accepted until it is demonstrated that the gains are worth the "risks", an issue that immediately arises is our satisfaction with raapo treatment. Are the gains worth the "risks" here? And how do they compare with innovation? Or do we apply a grandfather clause to raapo treatment? The issue, Robbins notes, "not only applies to procedures that are developmental or experimental but also to many procedures that are considered established and about which questions of risk are no longer raised" (1975, p. 4). And Eisenberg notes that the requirements for therapeutic trials may be standards of "safety and efficiency beyond those that can be offered for the best of medical practice" (1975, p. 96). With regard to raapo medicine, he cites the case of Benjamin Rush, who is considered to be one of the fathers of American medicine. During the plague of 1793, he remained at his post in Philadelphia, ministering to the stricken, instead of joining most of his colleagues in their escape to the country:

"Messianic in his zeal for purging and blood-letting, therapeutic maneuvers based on contemporary authority, he went from home to plague-ridden home, causing more carnage than the disease itself. Good

intention ... provided no substitute for knowledge then,
nor ... now" (1975, p. 96; emphasis added).

And Beecher notes that "a number of examples come to mind to suggest the need for healthy skepticism as to how readily established a standard may be," (1970, p. 92).

In discussing private and public good and harm, over short and long run, Barber suggests that "a rough functional calculus" be applied which "shows some definite net advantage all around" (1967, p. 100). What he is proposing has some elements of a decision approach. Some optimization criterion is to be applied to a 2 x 2 matrix, whose columns are private and public and whose rows are short and long run, with specific consequences in the cells. I am proposing that we begin considering the application of formal decision theory to the assessment of innovative approaches, since these are, after all, social decisions.

The decision criterion to be applied must be specified. Claude Bernard's implied criterion of no "ill to one's neighbor" is moderated by Beecher's "shades of gray" (quoted in Barber, p. 98). The decision criterion would be applied to a matrix whose columns are types of treatment and whose rows may be that which the treatments are to be applied to. These may be different diagnoses, or different assumed stages of an illness. In cancer research, for example, chemotherapy and radiation might be applied to cases where the probability of metastasis was $>.2$ and $\leq .2$, and all four empirically obtained effects (entries in the cells of the matrix) might help obtain comparative "expected values" (a decision criterion) of these two (or more) treatments for these probabilities. Similar matrices might be applied for other probability levels. No ready prescription is offered for the row entries, nor are the possibilities exhausted.

Outcomes need not be restricted to gains and losses, or benefits

and damages. Elsewhere (Goldiamond, 1974) I have noted that two treatments which equally control self-damage (physical constraints and occasional slaps upon head-banging by an autistic child), may have different effects on what new behaviors may be taught (none in raapo constraint, and progress toward developmental norms in behavior modification), and protection of civil liberties and right to treatment might also be considered (Goldiamond, 1975b). A matrix was offered to rationalize the tendency to overdiagnose and undertreat found in some psychiatric hospitals (Goldiamond, 1974).

What is being proposed is that the evaluation of benefits and damages of an innovative procedure never be assessed purely in terms such as how much damage are we willing to tolerate for how much benefit, that is, in terms of effects of the procedure alone, but that comparison with the benefits and damages of raapo treatment be the routine strategy. Formal decision theory minimally requires a 2×2 matrix, and a decision is not defined in terms of weighing alternative outcomes of simply one course of action. Ordinarily, it would seem that a control group provides such a possibility, but I am suggesting that raapo treatment be that control, or one of two controls. This might give a 3×2 matrix, with the columns being innovative treatment, raapo treatment, placebo.

Where the "expected outcome" data are available for raapo treatment, such data would be useful in comparing projections from innovative treatment as results are obtained. Where several types of treatment had been used, a historical analysis might supply cell entries which would be useful in establishing "expected values" of the treatments for different conditions. It should be noted that it is possible to construct such matrices only to the extent that the requirements of decision analysis (implicitly or explicitly) entered into data collection procedures. Where there are no data even approximating this requirement for raapo treatment, one might

question the bases for having accepted or continuing to accept this treatment as standard, and question whether it should be used as a standard against which innovation is to be measured.

The use of raapo treatment as a standard for defining innovation (that which deviates from raapo treatment) is carried to a logical conclusion when Levine extends this definition of innovation to the social sciences, namely, as that "which differs in any way from customary medical (or other professional) practice" (1975a, p. 24). The innovations would thus require all sorts of protections not provided in raapo social discipline. One example given of a parallel to the investigator-doctor role confusion is a criminologist-law-enforcement officer. But suppose some highly undesirable hole (solitary confinement) is raapo prison treatment, as indeed is the case (In one prison in Illinois a cubicle within a cube within a cube is standard), and suppose a warden-penologist wishes to see if such treatment is necessary (a general statement) and for half the prisoners so consigned, converts the cubicle to a larger room, provides options, and so on. He records differences between the two situations. Would we require the imposition of informed consent and all the other safeguards for this deviation from "customary [penal] practice", when they were not required for the standard procedures? A decision matrix might prove quite useful (procedures x assumed severity of offense) in convincing the outside world to adopt the change, or to whom to apply it.

All of the foregoing may be summarized by a common expression, when innovative treatments are assessed, comparative raapo treatments should be "up for grabs." By this process, raapo treatments might gradually be clarified as innovations progress.

This maxim should not hold where the treatment practices of a practitioner are under scrutiny, since the practitioner should not be faulted for what was then not known. Thus raapo treatment would remain as the safeguard it

has been for the practitioner who uses it, but would lose this position in the evaluation of innovative treatment. The two functions would be separated.

Separating the evaluative (research or demonstration) and treatment functions provides safeguards for the practitioner of raapo treatment. But what of the practitioner of innovative treatment? Given the uncertain nature of raapo treatment outcomes, and given the fact that research is not the only avenue to discovery, and that treatment may also provide such an avenue, the social and personal stakes in innovative treatment are high. I submit that the principle of concordance also extends to innovative treatment. Here, it is treatment concordance which is involved. With regard to analogous raapo treatment, whatever consent procedures obtain; whatever degree of prior specification of procedures and alternatives is required; whatever degree of evidence of effectiveness and evaluation in terms of cost of treatment, duration, and possible harm are required; whatever proscription holds against use of an explicitly designated procedure until it is evaluated further; whatever degree of post-hoc review is required, -- these might also be required in innovative treatment. In addition to protecting the social and personal stake in innovative treatment, such treatment concordance might also protect the patients (clients, students, etc.) at least as well as they are now protected by the analogous raapo treatments. Where such concordance exists, the fact that innovative treatments differ from raapo treatments should concern neither type of practitioner -- until innovative and raapo treatments are evaluated. As was suggested, evaluation of innovation would routinely call for simultaneous and comparative evaluation of analogous raapo treatment.

The social and personal ends (consequences) contingent on innovation and research are not served by confusing them, and are best protected by clear definitions and distinctions between them. That innovation (discovery) is not congruent with science was discussed in a philosophic context by

Reichenbach (1951), who distinguished between the context of discovery and the context of justification (p. 231). It is a particular set of formulations of the latter which distinguishes science, and it is "the adequacy of the empirical procedures [which] governs the adequacy of the experiment and minimally demonstrates the competence of the scientist" (Goldiamond, 1962, p. 310). What it is that is evaluated in this manner can have been suggested to the investigator "by a theoretical issue, by a procedural issue, by his own subjective experience, by accident, by mistake, by serendipity, or in some other way" (Ibid), including treatment. As was noted, the continued confusion between innovative and experimental is of concern to lexicographers. The formulators of social policy have other concerns.

Innovation which is governed by scientific contingencies should be considered as scientific in concordance with defining criteria of the relevant scientific communities, and innovation which is governed by treatment contingencies should be considered as treatment in concordance with such defining criteria of the relevant treatment communities. The concordance required for research in the context of treatment is that of both communities for the contingencies in their respective domains. The evaluation of innovative treatment would require evaluation of raapo treatment. Such joint-evaluation, since it is governed by scientific contingencies, should meet the defining criteria of that community, as well as raapo treatment concordance for both innovative and raapo treatments unless concordance were already there, as in evaluation through historical research. Evaluation of different raapo treatments would be similarly considered by both communities.

It would seem that the principle of concordance contributes not only to the definition of treatment and research, but also to evaluation of innovation and treatment, and to protection of the social and personal stake

in innovation, as well as to the protection of individuals treated thereby.

III. DIFFERENT CONTINGENCIES GOVERNING PATIENTS, SUBJECTS, AND RELEVANT PROFESSIONALS

In the discussion of occasions-consequences for treatment and research, it was noted that the patient and the systematic formulation are analogous, but patient and research subjects are not. This implies that patient and formulation will be treated with analogous respect (or disrespect) since social support for the systems involved may ultimately be contingent on how successfully the systems produce their assigned outcomes. This also implies that patients and research subjects, since their positions are not analogous, will occasion nonanalogous professional behaviors in the treatment and research enterprises, as enterprises. The conclusion that the protection of patients and subjects requires different types of review procedures is accordingly a valid one -- as long as the discussion is confined to the enterprises as enterprises. However, as will be noted in Section IV, there are overriding commonalities in other social contingencies, which dictate a different conclusion.

In treatment, an extended sequence of interactions between patient (student) and professional is often required for each. An operant chain is thereby described; the link reinforcers derive their reinforcing properties from their progressive relation to those consequences for which the whole sequence is required. On a day-to-day basis, the practitioner's treatment efforts along certain lines are reinforced or weakened by ensuing changes (depending on direction) of the patient, these then occasion further efforts on the practitioner's part, these are then strengthened or weakened, and so on. The three-term contingency is clearly evident. In this interactive arrangement, the patient's outcomes control the professional's behavior,

providing both occasions and maintaining consequences for it. The patient's behaviors are reciprocal: the presentation of complaints and reports of relief are patient behaviors which are the occasioning and reinforcing stimuli which bracket the practitioner's behaviors. These patient behaviors, as well as compliance with other "orders" (the "patient role") are maintained by the same consequences which maintain the practitioner's behaviors, namely, their progressive approach to the outcome which maintains the entire sequence. Thus the (patient-practitioner) "mutuality of outcomes" which is used to describe the terminal outcome of "successful practice" also applies to the links in the sequential chain. There is not only mutuality of outcomes but reciprocity of behaviors. As Parsons observes, "each participant receives in the short run a quo for the quid that he contributes" (1969, p. 338). It should also be noted that a third party enters into this mutuality. It is the social system, for whom this outcome is also meaningful, and to obtain which it supports the treatment system.

In experimental research, investigators are engaged in an extended sequence of interactions with their data. In operant and related single-organism research, the investigator's manipulations along certain lines are strengthened or weakened by ensuing changes (depending on direction) in the dependent variable, these then occasion further manipulations on the investigator's part, these are then strengthened or weakened, and so on. The three-term contingency is clearly evident. The orderliness of the data controls the investigator's behavior, providing both occasions and maintaining consequences for it. In most research using statistical inference, this progressive control by increasing orderliness is evident in a series of experiments, by one or several investigators. Ensuing experiments are governed by outcomes of the preceding ones. The outcome which maintains the sequence of investigator-behaviors in a single-organism operant investigation, or in a

series of statistical studies, is increased orderliness or systematization of statements. The third party here is the granting agency, for whom this outcome is also meaningful, and to obtain which it supports the research system.

Since the patient's outcomes control the practitioner's behavior, and the experiment's outcomes control the investigator's behavior, it can be said that the patients control the practitioner, and the "data control the experimenter." Indeed, the patient pays the practitioner, who is thus clearly identified as the agent of the patient. In the case of research, it is the social system, through its granting agency, that pays investigators. They are thereby the agents of the granting agency. They write reports for it, agree to provide time for it, and so on. The mutuality of outcomes and reciprocity of behaviors which characterize relations between patients and practitioners in treatment, also characterize relations between granting agencies and investigators in research. Patient and granting agency are in parallel relation. Payment is, accordingly, critical, and not extraneous, as Levine suggests (1975b). It helps define and separate agent from client in both treatment and research, in addition to filling other functions to be discussed in Sections IV and V.

Research subjects do not enter this realm of discussion. They play yet a different role. This role is evident if one first summarizes profession-agent roles in treatment and research.

- A. Treatment:
 - 1a. Professional is agent of patient
 - 1b. Patient is client of professional
 - 2. Professional agent is paid by client patient.
- B. Research:
 - 1a. Professional is agent of grantor.
 - 1b. Grantor is client of professional
 - a. Professional agent is paid by client grantor.

- C. Research Subject: 1a. Subject is agent of professional.
 1b. Professional is client of subject
 2. Subject agent is paid by client professional.

Vis-a-vis the subject, the professional is in a reversed position from either of the two preceding ones. Since the professional is an agent of the granting agency, the subject by extension is also. The subject can be described as being in a "line position" rather than in one of continual interaction with the professional or the granting agency.

A fourth relation of interest can now be considered. This is the situation where research is conducted in the context of treatment.

- D. Research-Treatment: 1a. Professional is agent of patient (A-1)
 1b. Professional is client of subject(C-1)

Since the subject is also the patient, the same person is both client and agent. If the practitioner is also the investigator, this confounding holds on this side, as well. If practitioner and investigator are separate in person, both may be similar in role, since they are agents of the same client institution (hospital or university) which pays their salaries. Unless the relations are made explicit, and steps are taken to separate the functions (some of which will be discussed), there will be problems in a variety of areas, including coercion and consent (see Gray, 1975, for some of the contamination).

Since the investigator pays the subject and the patient pays the professional, when investigator and professional are the same, and subject and patient are the same, each should both pay and be paid. Indeed, the cancellation or lowering of patient fees in many clinical-research units supports this statement.

Means-ends relations

It is frequently asserted that since the research subject lacks whatever

protection the patient gets from the mutuality of patient-practitioner outcomes, the subject requires special protection. The particular jeopardy in this case is that the subject may be used as a means to obtain the investigator's end, namely, general knowledge. This may not only be unhelpful to the subject, it may be harmful. Where research is conducted in the context of treatment, it is at best simply extraneous to the outcome of treatment, and at worst, in opposition to it.

In research, human subjects are considered specially subject to abuse since a variety of social consequences are contingent upon the investigator's contribution to knowledge. Dependent on publication are prestige, promotion, income, research funds. These outcomes for the professional can not be characterized by the mutuality of patient-practitioner outcomes which characterize treatment. Nor are they even congruent with the payment or course grade used to maintain subject participation. The subject is therefore liable to abuse -- the consequences cited are strong ones and are not shared by the subject.

In treatment, however, similar consequences are also likely to hold. Presumably, dependent on the practitioner's success in treatment are such consequences as prestige, promotion, income, and access to facilities. These outcomes are not characterized by mutuality of patient-practitioner-social outcome. Such divergence in outcomes between professional and client was the occasion for the anguished cries of Linus in the Peanuts comic strip series when he discovered that his teacher was getting paid; he was broken-hearted to discover she was not governed by his learning. (The consequences for students in elementary school systems for which the governing outcomes are other than student progress are more disastrous.) The dimensions along which critical differences may lie, when one views the systems as systems, are in the different socially-defined contingencies previously discussed, which distinguish treatment from research. The ethical

issues, in part, reside in the fact that the outcomes determined by the social systems in the two cases do not consider research subjects. The outcomes are, in one case, treated patients, educated students, trained technicians, and so on, and, in the other case, are treated and better organized systems of knowledge. Where there is abuse, it resides partly in the specific procedures used by particular systems, and partly in the relations which research and treatment share with a host of other social institutions, and which will be discussed in Section IV, and not simply in the use of the subject as a means, since the patient may also be used in this manner.

IV. ABUSE OF POWER: COERCION AND CONSENT

A variety of interpersonal relations including those of research and treatment may be described as power relations. The common contingencies related to this common descriptive term make possible the abuse of power they share. The issue of consent is addressed, in part, to such abuse in the context of coercion. The present section will consider coercion as it applies to the abuse of power and to consent. Section V, which follows, will consider informed consent in the context of contractual relations.

Ethical issues are raised when power is abused. Interpersonal power relations may be found not only for investigators and their subjects, and doctors and their patients, but for governors and governed, officers and enlisted men, employers and employees, teachers and students, ward committee-men and appointees, husbands and wives, parents and children, to mention but a few. In each of these, power flows both ways, but the alternating powers, unlike alternating currents, differ in topography. The focus here will be on the first party, who may be said to be the "exclusive vendor" or distributor of the occasions and consequences which critically bracket socially-relevant behavior of the second party and may thereby control it. In this model, the comparable control exerted by the second party is

trivial. Since control over exercise of the powers of the first party does not derive from consequences supplied by the second party, it would appear to be under other control.

One model used to describe such other control is "self-control," which may (or may not) be related to an ethical code. That such codes are addressed to the asymmetric power flow described is suggested by consideration of "the moral law as such [as being governed by] a transcendent motivation" (Jonas, 1969, p. 232; cf. Goldiamond, 1968). Stated otherwise, it transcends control by the consequences supplied by the second party. Violating the code is immoral or unethical and censure is applied by peers, that is, by those with parallel dispensation powers.

The appropriate exercise of these powers may be considered to be a trust as defined by an explicit social fiduciary model, whereby kings, officers, employers, bankers, and husbands exercise their powers for protection and benefit of their wards (not only did the French general address his enlisted men as "mes enfants", but the Russian enlisted man addressed his commander as "Otyets", i.e., Father). Fulfillment of a trust is involved. Hence fiduciary (L.fidere, to trust).

Needless to say, when the behaviors by which one party controls the behaviors of a second are not controlled by the second, and the first party is then considered to be under self-control or control by a code of ethics, the underlying assumption is that the first party's behavior is under some form of control. The necessity of internalizing the control, in the form of ethical adherence to a trust, derives from dissatisfaction with an explanation of control by a subordinate. However, the control may derive from a superordinate system which establishes and maintains the institutionalized relation between both parties, both of whom are therefore its agents. The social behavior of establishing and developing institutionalized trust

contingencies, like the support given the treatment, research, and legal institutions, is maintained by the outcomes the system gets when it provides such support. As in the case of the use of a term as difficult to define as intent, the problem to which a term as difficult to define as internalized adherence is addressed may be resolved by consideration of social contingencies. That they bear on an important social problem is indicated by consideration of at least one form of abuse of power.

Such a case of abuse of power is defined when a member of the first party makes the social contingency (which governs the institutionalized relation) contingent on behaviors by the other which are outside the social contingency, or applies the social contingency in other ways to get such behaviors. The David and Bathsheba episode is an early instance and provided the occasion for an explicit moral sermon. In a more modern vein, Peters, in Ethics and Education, notes that "It is one thing for a university teacher to have an affair with his colleague's wife, but it is quite another thing for him to seduce one of his students" (1967, p. 210). The latter case permits an abuse interpretation: grades and prestige, socially approved to govern academic compliance, are made contingent on a different pattern of compliance. Thereby, it will be noted, society is not obtaining the occasion-consequence reversal which reinforces social support of universities: the untrained student has not become (academically) trained thereby. The teacher, accordingly, may be jeopardizing social support of universities. His university-supported peers may therefore suffer and may then censure him in some way. And the social system is frustrated (nonreinforced). He has "hurt his profession" by his "antisocial behavior." These terms approximate the relevant terms in the social contingency. He "has violated his trust" refers to the fiduciary model. His "unethical abuse of power" refers to the asymmetrical power model. All derive from

the social contingencies discussed.

An interpersonal relation in which power derives from coercion is fertile ground for unethical abuse since it permits easy control of behaviors outside the contingency. Thus, a patient under tremendous distress which can be alleviated only by an emergency treatment is subject to abuse by the sole dispenser of that treatment. The dispenser can make dispensation contingent on a variety of requirements -- including consent for research as well as for a variety of treatments. The validity of consent obtained under such conditions, no matter how well-informed the consent was, might be questioned. It might be argued that the procedures represented a flagrant abuse of power, and that the consent was spurious. It was obtained under coercion and was not freely given. The person was not in a position to consent.

It is evident that in order to consider the validity of any type of consent, we must first examine freedom and the coercion assumed to negate it.

Contingencies of freedom and coercion

Freedom will be defined in terms of the genuine choices available. Choice will be defined by degrees of freedom (df), a scientific term which will be used here to define the number of variables in a system whose values have to be specified to determine the system. The volume of a cube is given by $V = lwh$, and given any three values, the fourth is determined (l to determine h , V to determine l , and so on). Thus, $df = 3$, as it is to specify the coordinates of a point in 3 dimensional space. Our concern is with alternative behaviors, and we shall use decision theory as our model. Here, at least two well-defined sets of behavior are required (for example, being at home or at work are well-defined alternatives, but being at home or elsewhere introduces the poorly-defined set of elsewhere, which can include a moon and Jupiter), and the sets are related by the equation $a + b = 1.00$. Since the value of either then determines the value of the other, $df = 1$. Where

$a+b+c+d+e = 1.00$, $df = 4$. There is a greater degree of choice, that is, there are more degrees of freedom. The df term is a useful one. It not only suggests that freedom is a matter of degrees, but also implies that coercion (to be defined presently) is also a matter of degrees.

The parallel between intuitive notions of freedom and the df usages is suggested by the fact that when the only work available is in a mine, and otherwise the person goes hungry, then working in a mine may not be considered a matter of free choice and, indeed, union experience has taught that miners are then more vulnerable to abuse than they are at other times. With regard to work as the referent, since there are no work alternatives, $df = 0$. There are no degrees of freedom. This accords with the common expression. If there is a choice between mine, mill, factory, or farm, then there is greater freedom, workers can feel "more independent," and abuse is less likely. Here, $df = 3$. Freedom, as defined intuitively or by values of df, is greater.

Freedom is related to coercion in the following manner. To the extent that a critical consequence (to be defined) is contingent solely on a class of activities, then dc, or degree of coercion, is inversely related (the term is used figuratively, rather than exactly) to df. Assuming temporarily that survival is such a critical consequence, then when one works in the mines or starves, coercion is maximal, since the maximum value of dc will be given when $df=0$. Where there was a choice between mine, mill, factory, and farm, coercion was less since df had a higher value, but for the set of unskilled labors represented and starvation, there is coercion and the complaint of the uneducated that their freedom of choice is confined to jobs undesired by others, becomes understandable. At any point, of course, the set of all possible tasks as opposed to survival can be considered coerced. Accordingly, the issue is never coercion versus no coercion, since $df + dc = 1.00$ (roughly. That is, one defines the other, and they are codefined). The issue is the

amount and type of coercion we are willing to accept, and the protections against abuse we set up. These should be defined.

It was noted at the beginning of this section that choices had to be genuine. Genuineness relates to contingency repertoires. Someone with a high school education who scans the want-ads, has no choices when all openings require a college education. He does not have a choice between working as a miner or as a physician when there are openings in both fields. Here, $df = 0$ because of the behavioral repertoire. Where job availability is not announced, or is circulated in channels not available to the seeker, or in a language the seeker cannot read, the existence of the appropriate repertoires is irrelevant, and $df = 0$ because of the opportunity component of the contingency repertoire. Further, there is experimental evidence that given occasions which are in the repertoire, given behaviors in the repertoire, and given potent consequences, the individual may persist in behaviors which result in loss of consequences, or may switch to those which rapidly produce them, depending on the manner in which the consequences were previously contingent on behavior (Weiner, 1972). Finally, the consequences enter, as when the type of food available is forbidden by a powerful religious code. Failure to distinguish genuine choice from simple availability of alternatives, no matter how well their availability is made known in an informed consent procedure, is reminiscent of Anatole France's statement on the impartiality of the law which "in its majestic equality forbids the rich as well as the poor to sleep on the bridges, to beg on the streets, and to steal bread" (Le Lys Rouge, Chapter 7).

Some consequences are at certain times more critical than others, depending on a variety of conditions whose investigation is being pursued in the

laboratory. In one branch of such research, the organism may be offered a choice between two consequences, with response costs and other variables held equal. The extent to which one is valued more than the other can not only be measured but can be manipulated experimentally. One method is through deprivation, often referred to as need, or drive. Organisms at full body weight may prefer the opportunity to exercise over the opportunity to eat, but if they are deprived of food, the order of preference may be reversed. Other procedures may be utilized by the investigator, and all of these will be subsumed under the general term of conditions which make a consequence critical, that is, one which is preferred in all choice situations.

Coercion accordingly may be defined as most severe when there are no genuine choices ($df = 0$), and the consequences contingent on behavior are critical. Coercion obviously relates to consent, since to the extent that coercion is involved, giving consent may simply be one more behavior added to the packet required to obtain the critical consequences. Where indignities are required, consent may simply become another indignity required to get the critical consequence or to avoid its absence, to state it in terms of negative rather than positive reinforcement. (For fuller discussion of coercion under negative reinforcement, see Goldiamond, 1974, and for both negative and positive reinforcement, see Goldiamond, 1975a, b.)

Two types of institutional coercion will be distinguished. In the first, the institution which delivers a critical consequence has set up the very conditions which make the consequence critical. In the second, the institution which delivers a critical consequence has not made it so. It is merely capitalizing, so to speak, on an opportunity provided by a state of nature (actual or manmade). I shall designate these as Institutionally Instigated Coercion (IIC) and Institutionally Opportune Coercion (IOC). They will be considered separately.

Institutionally Instigated Coercion. A familiar research example with a nonhuman subject is the conventional operant pigeon experiment. Here, the experimenter (or the assistant agent) deprives the pigeon of food and brings him down to 65-70% of normal body weight. The investigator then makes access to food contingent on required patterns of behavior. By careful programming of these patterns, the occasioning stimuli, or both, it has been possible to establish extremely complex patterns of behavior and discrimination, almost without error. In technical jargon, delivery of food serves to reinforce the response required to make it available; it is the experimenters who have so arranged it that delivery of food serves as a reinforcing stimulus. This they have done through prior deprivation of the organism. They need not deprive the organism to achieve this effect. They may simply provide a few doses of heroin to an animal with an indwelling catheter. Yet other conditions may be manipulated.

If deprived pigeons could consent, and were required to do so, before undertaking the training program which is their only means of obtaining food, such consent could be considered as having been obtained under severe coercion, rendered all the more severe by the fact that it was the experimental system itself which made potent the reinforcer it provides. To, say, a four-link chain required to make food available, for example, pull a wire, turn a counterclockwise circle, press a pedal which illuminates a disk, and peck that disk 15 times, then get food, a sixth and fifth link would then be added: intelligently discuss your options, then sign consent to participate, then pull a wire, turn a counterclockwise circle, press a pedal which illuminates a disk, and peck that disk 15 times, and get the food, blessed food. The coercion would not be reduced; it might even be exacerbated.

Consider the case of human inmates of a penitentiary. If they participate in a particular biomedical research project, such cooperation, by

demonstrating to the parole board the "acquisition of prosocial attitudes", renders them eligible for earlier parole. Stated otherwise, restoration of liberty or earlier release from incarceration (negative reinforcement) is contingent on an institutionally-provided opportunity to participate as a subject. The bicentennial notwithstanding, we do not need a Patrick Henry to remind us how critical a consequence liberty can be. The coercion is made all the more severe by the fact that the very penal system which makes the delivery of liberty a reinforcer is part of the same judicial-penal system which deprives the inmates of liberty. The analogy with the pigeon is almost a homology, and the meaningfulness of any consent obtained under these conditions would be questioned. (Conditions under which prison research does not fall into this category will be considered shortly). The same strictures hold even if the prisoners are offered their choices of rehabilitative programs, if each is linked to earlier parole. These then become elements in a coerced set.

In one form of "brain-washing" the person is deprived of the usual social support through isolation by physical or pharmacological restraints, or through isolation from the hitherto supporting community by a special communal arrangement. Social support by the new group is then made contingent on individual behaviors which meet its requirements. The most effective behavioral requirements are those behaviors whereby the person, by assaulting the sensibilities of the original referent group, is further isolated from that group by his or her own behavior, making the support of the new group all the more critical. The parent who makes a child dependent is a clinical example.

What is probably the starkest case of institutionally-instigated-coercion is the use of torture to obtain evidence. Relief from pain is made contingent on behavior which meets the system's requirements. It is the system which

supplies the painful stimuli which make relief from it a potent reinforcer. No civilized court would accept consent obtained under such means. Their equation with coercion makes clear the contingencies involved, which are often otherwise obscured by rehabilitative or other idealistic statements.

Continuing on the same stark note, we routinely question the morality of those who create shortages and then profit from the delivery they monopolize.

In a less dramatic manner, the requirement of a department of psychology that each student in an introductory class participate as a subject in some experiment to obtain a passing grade belongs in this coercive category, to the extent that passing this course is critical to the student's academic program. However, the coercion is mitigated by its trivial nature, and the contribution of the experiments is typically in accord.

(In a possibly facetious tone, the statement that "the lawyers" have us in their clutches may reflect not only their inescapability for us, but the existence of some overlap between the legal system which provides relief and the system which sets up the conditions which make its delivery a potent consequence. [The tax lawyers who write rules which only tax lawyers can decipher seem to be a case in point but, in actuality, social and political considerations often govern the rules.] The suggestion that legal practice be reviewed by committees composed of representatives of other interest groups may reflect not only retaliatory pique against legal advocates of "consumer" groups such as patients, prisoners, and students, but may also reflect the regulator-regulated issue raised by expertise which was noted earlier, as well as other professional issues. There is, after all, a legal profession which provides services to clients through socially-supported systems. It would be surprising if some of the issues raised in our discussion

of treatment and research did not apply here, as well. There is legal research as well as legal service delivery.)

In all events, consent to participate in some activity, where the consequence contingent on participation was made critical by the consequence-delivery system, should be considered as having been obtained under coercion. This does not automatically exclude such consent or such activities from the pale since, as was noted earlier, the issue is not freedom from coercion, but rather the degrees and type of coercion we tolerate, and what safeguards against abuse these require. It should also be noted that it is the peculiar nature of the contingencies described which designate the activities and consent as coerced. The same activities and consent can be governed by other contingencies, which are not institutionally coerced. Given such contingencies, and where the activities are socially and personally beneficial, conditions appropriate to their support might be considered. To label an institution as coercive and therefore to assume that all related activities are coerced, is akin to certain characterological descriptions of individuals or classes of individuals which then subsume all individuals and all behaviors. Both ignore the different contingencies which govern the different and varying behaviors of any complex social institution or, for that matter, any complex social individual.

Institutionally opportune coercion. There are situations in which the system which makes critical consequences contingent on institutionally-defined behavior has not produced the conditions which make these consequences critical. The "helping professions", of which medicine is a prime example, belong in this category (iatrogenic disease is an exception, but is considered an undesirable). Where $\underline{Jf} = 0$, and the consequences are critical, coercion is still defined. It is not lessened by the fact that it was not institutionally instigated, nor is it lessened by its social prevalence,

inevitability, or desirability. The coercion is exacerbated when the institutions set up to treat the problem are operating under a "legally granted monopoly" over "a captive audience" (Freund, 1969b, p. 315). In effect, a critical consequence is not only solely contingent on submission to a particular form of treatment, but in addition, that form of treatment is provided solely by a system with monopoly control over its dispensation. The coercion possibly provides the system with an opportunity for socially appropriate practice or for abuse, which opportunity is not as generally available outside it. Accordingly, any consent obtained under such conditions requires careful examination.

In the next few sections, I shall consider some possible arrangements whereby consent may be considered as possibly meaningful, when the person's entry into the system was coerced, whether coercion was institutionally instigated or institutionally opportune. Where these require different consideration, this will be noted. Three major arrangements will be noted, separating critical consequences from the activities, converting mutuality of outcomes to mutuality of contingencies, and noncoerced participation in programs specific to coercive systems.

Separation of critical consequences and activities

In a prison situation, when earlier parole is independent of whether or not an inmate participates in a program, then consent to participate in that program is not related to the release which the penal-judicial system made critical. If a church provides food during a famine, whether or not the person attends church, then it is clearly not capitalizing on this opportunity. Similarly, if the same treatment is available whether or not the person consents to serve as a research subject, then the situation is similar to the church arrangement. Separation of critical consequences and activity

simply removes this form of coercion. It does not, however, automatically instate other requirements to make consent meaningful. These will be considered later.

If making a critical consequence such as treatment contingent on research participation raises questions of appropriateness, it is partly because research is considered extraneous to the occasion-consequence reversal which characterizes treatment, and partly because of social values attached to relief of distress, among others. These considerations would also hold for making treatment contingent on ability to pay. It is highly likely that the United States will soon join other advanced nations which have eliminated this requirement. However, in the meantime, an ethical and social policy problem is posed by hospitals which make reduced payment or no payment contingent on serving as a research subject. It was noted earlier that this meets the exchange system logic of patient-pay, subject-paid, research patient-pay-paid, therefore fees cancelled. However the goodness of its fit to this model, providing free services in return for research participation poses questions about the ethical fit. Where treatment is contingent on payment, the treatment consequence is critical, and the type of treatment offered is not genuinely (as defined earlier in terms of contingency repertoires) available elsewhere, the payment is coerced. That it is a social necessity is beside the point -- it is still coerced. For someone who lacks the financial resources (repertoire), making service as a research subject a substitute for payment, substitutes research service for coerced payment in the coercion arrangement described. It must then be recognized that since research is thereby coerced, it is open to abuse, and consent must be carefully examined. Few commentators have been sensitive to this issue, but Eisenberg is on target when he doubts "that we will find a way of

distributing risk across all segments of society until we have a national health service for all citizens" (Eisenberg, 1975, p. 97). Under such arrangements, enrollment in a research-treatment program would be governed by considerations other than research substitution for coerced payment.

Payment also enters into prison research (or special treatment programs). Where early parole and other institutionally-instigated critical consequences are not made the consequences contingent on research-treatment participation, this form of coercion is removed. Money, of course, is an important consequence though not necessarily a critical one for people who are otherwise fed, sheltered, and clothed. To the extent that it approaches being critical in a situation (as judged by its selection above other consequences), and to the extent that df approaches 0, the required activity approaches coercion. Critical nature and df will be assessed separately.

With regard to critical nature, or uses of money to an inmate, it should be noted that the penal system deprives an inmate not only of liberty, but also of other amenities available in the world outside. Accordingly, institutionally-instigated coercion is defined not only when the system makes liberty contingent on some behavior, but also when it makes the other amenities of which it has deprived the inmate contingent on behavior. Where money buys freedom, it is evident that its payment has been coerced, and the behaviors upon which the wherewithall to pay is contingent are also coerced. By the same logic, such coercion also enters into payments for amenities of which the prison system has deprived the inmate, and into the research/work programs which produce such payment. Before such programs are hastily condemned, an important qualification raised earlier should be reiterated. This is that coercion is not absolute, but there are degrees of coercion as well as of freedom. As was then noted, when work is the issue, availability of work in the mines, mills, factories, and farms is described

by $df = 3$. However, given the set of menial work (mines, mills, factories, farms) and a starvation alternative to that set, $df = 0$, and menial work is coerced. This can be extended to "higher" levels ad infinitum, lending support to Ogden Nash's verse, "I could live my life in ease and insouciance / were it not for making a living, which is rather a nounciance." This form of coercion occurs in the world outside and is acceptable -- and, indeed, is necessary there (exceptions such as inherited wealth exist, of course). The principle of concordance with such outside facts of life may then be extended to define an acceptable form of work-coercion in the institution, as well. The general rule involved would take a form such as: to the extent that the institutional work programs follow the work-requirements of inmates (or people with their skills in legally accepted work) in their usual world, institutional work-requirements provide an acceptable form of coercion. Exceptions derive, of course, from criminal work, e.g., the system would have to provide a forger with other work arrangements. Similarly, inmates who had never worked might be given work concordant with that available for people with skills and experience similar to theirs, or might get necessary training. Along these lines, it should be noted that at least one European prison provides for daily medical practice outside the walls for physicians serving their terms, and similarly provides for construction and factory work, etc., for skilled and unskilled workmen. Earnings on the outside are at the going rates there. In these institutions, the inmates also pay, from their earnings, for their room and board, as well as the extra costs which their incarceration incurs. Such institutions are special institutions with special programs prior to such arrangements, and during them. It should be noted that the world outside provides payments for research subjects, and in some cases, such payments are competitive with those for work. (Some nutritional research programs, for example, have provided salaries for college students during their

summer breaks.) To deprive inmates of such work/research possibilities has the effect, at the very least, of depriving them of options concordant with those holding outside. Other effects have been cited by advocates of penal reform or abolition, and will not be discussed here.

The value of n in $df = n$ is, of course, resolved by application of the foregoing concordance principle. As many options might be available as are given by the socially-accepted skills of the inmates, the positions available and the exigencies of the institution. And there is no reason to exclude the option of serving as a research subject, providing the payment, conditions, and protection are concordant with those provided for a volunteer outside for whom other options are available.

This approach to research participation might also enter into institutions whose coercive control is opportune, rather than institutionally-instigated. Stated otherwise, arrangements for research participation of patients undergoing treatment might be concordant with the arrangements for research participation of paid normal subjects of the type described. Where the research is related to treatment, and the problem is a rare one, the subject/patient is then not a routine research employee, but one with special and hard-to-find qualifications. Arrangements should be commensurate and concordant with those provided for skilled employees outside. Where the problem is more common, subject/patients should be easier to find, and the situation is more competitive. Even under such conditions, as anyone who has conducted long-term research knows, the investment in the research patient or research pigeon is considerable, and the concordant arrangements discussed earlier would also hold here. It is assumed, of course, that for the patient, research is an option and not a requirement for treatment. Otherwise, institutionally-opportune coercion holds, and the research-patient may be in greater jeopardy than a prisoner with other-than-research options.

The issue of social versus individual needs is, I believe, inappropriate to this context. Edsall (1969) argues, for example, that individual treatment needs must occasionally be subordinate to social research needs, citing the drafting of young men as soldiers (pp. 472-3). Indeed, Beecher asserts that "parents have the obligation to inculcate into their children attitudes of unselfish service. This can be extended to include participation in research for the public welfare if judged important and there is no discernible risk" (1969, p. 282). The children of mothers on diethylstilbestrol (DES) some twenty years ago might judge that "no discernible risk" to have been otherwise. The war situation is not analogous. The possibility of death and disfigurement is well-publicized. Such outcomes for the enemy accord with social contingencies, and the same fate for the local army accords with social contingencies of the enemy. It might be said that the volunteer concentrates on the social contingencies of his side, and the draftee concentrates on those of the enemy -- hence the coercion applied to his recruitment. Any analogy to research, whether in a medical setting or in a prison is far-fetched. As Jonas notes: "No one has the right to choose martyrs for science" (1969, p. 222).

Converting mutuality of outcomes to mutuality of contingencies

In a treatment system, it is the individual's responses (behavioral or physiological or both) which provide the occasions and outcomes whose reversed relation ultimately supports the profession and its professionals. To the extent that the individual's behaviors are brought into the same contingencies which govern the professional's behaviors, the professional's task is simplified. This requires that both work toward the same goals, or be motivated by the same outcomes, or that their behaviors be governed by the

same consequences, to use three different descriptive systems. This holds for research as well as treatment. We shall consider treatment first, since such mutual outcomes are assumed to characterize treatment systems. Despite the mutuality of outcomes such systems are organized to deliver; the treatment-relevant behaviors of individuals and professionals are often also (or instead) governed by different consequences. These may frustrate one or the other or both. Further, the individuals and professionals may not be apprised of what the other is doing. They may not be apprised of the relation of outcomes to the requirements of the other. Any of these may make informed consent meaningless. Accordingly, it may be worthwhile to examine how a system which is organized to deliver common outcomes might set up arrangements which facilitate such delivery, and under which arrangements informed consent might be meaningful. We might then see how these arrangements could be extended to a system in which it is assumed that common outcomes do not characterize individual and professional -- the subjects and investigators of research systems.

Although treatment systems are characterized by "mutuality of outcomes" it was noted earlier that they are also characterized by "reciprocity of behaviors." The physician orders and prescribes, the patient obeys and follows; the teacher teaches and assigns, the student learns and follows; the trainer trains and provides experiences, the trainee learns and utilizes. Accordingly, although the culminating outcomes are mutual, the behaviors required are not. Further, the behaviors of one are the occasions-consequences of the other. The analysis suggests that regardless of identity in culminating chain outcomes, the contingencies in the links of the chains are different in every component for professional and individual. Occasions, behaviors, consequences differ. For the individual's behaviors to be optimally governed by the same consequences as are those

of the professional then, not only must the individual's behaviors be governed by the same general outcomes as the professional, but the explicit occasions, behaviors, and consequences of the links in the chain must also be the same for both professional and individual. To make the contingencies the same suggests that it is only when individuals have access to the same data about themselves which the professional has that it becomes possible for these to come to govern their behavior, as they do govern the behavior of the professional. And in the difference between "come to govern" and "do govern" lies the professional training of the practitioner (The importance of past histories for a contingency analysis was noted earlier in the discussion on genuineness of choice as it relates to contingency repertoires. Among the major considerations was the "manner in which the consequences were previously contingent on behavior"). And I believe it might then be part of the professional's task to educate the individual. The education need not be of the kind or depth which produces a skilled professional. It might be one which simply supplies the individuals with the tools for analysis and change in the problem areas of treatment concern. The individuals are the experts in the data and conditions of their own lives. If they are taught where and how to look, they can supply data and suggest relations which professionals can use to advantage for the solution of the presenting individual problems. Such data are otherwise not available. And individuals can also begin to analyze their own responses and occasions of concern, and try to figure out what to do about them, trying this tack and that, even as professionals analyze the same responses and try out different approaches -- procedures which they and the common language confuse with experimentation. Professionals keep written records and are guided by them. The system suggested would require individuals to do likewise, and professionals would have access to their records in

concordance with the individual's access to professional records.

It should be noted that as chronic problems increase in importance, and as the influence of the environment is coming under increasing scrutiny, at least one system of treatment, namely, medicine, is turning increasingly to such individual self-management. Health delivery systems are trying to train individuals in self-examination (e.g., breast cancer) and self-monitoring (e.g., home sphygmomanometers), and physicians are beginning to substitute education and joint-decision making for the assumption that if they fulfill their trust in a fiduciary relation with their patients, these wards should cooperate and meet their obligations of obedience and recovery.

A treatment system which requires individuals to keep explicit records in concordance with staff records can readily be converted into a research system, as well. The extensive data which such records provide are, as was noted, otherwise not available. They provide information about responses of the individual under different conditions, and about the settings in which the problems occur which can be useful for research. Just as professionals often interpret the same data differently, the possibility of different interpretations of data from the same individual records may suggest itself to the individuals when they are required to interpret, or to individual and professional in their regular conferences. And just as in the course of professional conferences, the resolution may be to wait, to get more data, or to try this and try that. And it should also be noted that waiting (collecting more observations over time), or getting more data (running the same subject under more conditions), or trying this and that (manipulating different variables) are also means employed by experimental investigations for resolution of problems or

conflicts in explanatory systems. To the extent that the recording system which is supplied to the individuals, the interventions suggested for them to make, and other procedures are in concordance with those behaviors which enter into the definition of a research contingency, individual records can contribute to research. Is such research use of records and interventions separate from treatment use? If one views treatment in the context of self-management for prevention, melioration, or maintenance, then research use by the individual becomes necessary for treatment use by both individual and professional. Finding out about oneself, about "how I function," through distinguishing poor "explanations" from better ones, can be quite important for self-management or for improved professional management. And the "context of justification" of the scientific method is an excellent means for distinguishing acceptable formulations. Just as the treatment professional educates in the formulations and procedures of that area, the research professional educates in the formulations and procedures of that research area. In a research-treatment system of the kind described, the individuals may gain insights which are important for the practical resolution of their problems. The investigators may gain insights into those general functional relations whose resolution is important for the resolution of systematic problems in their disciplines. In such a research-treatment system, research and treatment go together because each is required for the other. Individual and professional are both "research and therapeutic allies" who share what intelligence the joint effort requires be shared, while having their own separate sources.

This setting describes for research and treatment the "collegiality" between individual and professionals which Parsons (1969) sees as ideal, and which Mead (1969) reports as obtaining in field anthropology (at least in those projects in which she has been involved).

Where the treatment does not require research for its fulfillment, treatment can take place within the congruent-contingency system discussed for treatment alone. Individual and professional are then "therapeutic allies" who share what intelligence about each other their joint effort requires, and reserve to themselves what is not required. For research alone, the congruent-contingency system would involve investigator and research subject. As "research allies" they would share and reserve corresponding intelligences.

In certain treatment areas (clinical, educational, or training), the outcome-producing program is well-formulated, with each step having been validated experimentally. In programmed instruction (p.i., cf Hendershot, 1967, 1974), the title of the text gives the outcome. Each of the frames in the text resembles a mini-contingency. An instruction appears, the student responds, usually by writing in a blank provided, the appropriate answer is then available for comparison. If there is a response-answer correspondence, the student is then presented with the next frame, and so on. Thereby, outcome repertoires are established which are far removed from those with which the student entered (The derivation from operant laboratory research is evident). The instruction which opens the frame, and the opportunity to move ahead (a consequence), contingent on adequacy of the student's response, may be considered as professional surrogates. They are always explicitly presented -- if the individual does not advance to the next step in "treatment", the reason is clear. (In a branching program, the student may be detoured to other steps, i.e. to differences in treatment before the main program is rejoined.) The students have access to their own performance and its adequacy at every step. (The steps are longer in the classroom-systems application known as p.s.i., where the instructions may be entire lessons, cf., Sherman, 1974). Although individual and professional

are not colleagues, or therapeutic or research allies, the explicit presentation to the individuals of the same information about them which the professional has (albeit by a surrogate professional), which enters into collegiality, also holds here. In the form of p.i. known as computer-assisted instruction, this electronic surrogate-professional functions almost as freely as a professional, (cf. Markle, 1975).

One implication of the quest for collegiality in the p.i. context should not be overlooked. The implication derives from the question: when are individuals and professionals colleagues in such programs, if ever? Students are presented with detailed steps, hence are not allied with the professional in their choice of them. The question is answered through reference to the development of the program. Here, there was opportunity for collegiality between program developer and individuals in the analysis of each step and its judgment as wheat or chaff. The developmental research is done in the context of treatment -- teaching, in this case. Here, there is room for considerable flexibility and trying this and that which, in a good program, is concordant with research behavior. Once the program is developed, it is simply available for application, and there can be several different programs which explicitly produce the same outcome in different ways. The parallel with clinical treatment is evident. The major implication is that collegiality may be necessary when the steps in the program (linear, or branching) have not been validated. Further, such development would require both treatment and research. And a corollary is that when the program is developed, it is still necessary to provide individuals access to the same data the professional gets.

The foregoing arrangements are obviously limited in their applicability. Among other limitations, they assume extended interactions over time. In treatment, such interactions are found in chronic care, education,

or training. They are also found in acute care when coupled with long-term recovery, or maintenance, or prevention programs. In research, extended interactions are found in laboratories which require extended experimental intervention, or where acute studies have long-term effects. Establishing arrangements of the type discussed is not an easy task. It requires careful and long-term contingency analysis which operant investigators and practitioners are familiar with, but in an area which is generally foreign to them, and whose required formulations have not been considered in the simpler operant arrangements studied thus far.

Although such arrangements would seem to be of only limited applicability to acute care or acute research (those situations where interactions between individual and professional cover only a short span of time and are confined to a few episodes per patient-subject), they may suggest some principles which might be applied. This would hold especially if the episodes are considered as condensed interactions which follow the same rules as the more chronic ones. They occur too rapidly for the analysis which the more leisurely and more magnified chronic situation permits.

Other settings and types of relations or problems or individuals may also suggest limitations. Nevertheless, the extent to which collegiality arrangements apply there might be considered.

An example of one such research-treatment system is provided by our laboratory-clinic (Goldiamond, 1974). We have been developing and working with such an explicit congruent-contingencies system. We have thereby been requiring individuals to keep daily records of the problem-relevant contingencies of their lives, even as we require of ourselves. We have been trying to have them analyze these records, even as we would. The records are used by us for basic research in behavior analysis and

behavior change in the context of treatment. Most of our patients have come from the well-educated middle class, as befits a university clinic, but lately we have been doing research in heroin abuse and have found the recording system to be applicable for urban poor with little education. As an illustration of how collegiality arrangements of the type discussed can lead to application of professional analysis and intervention by patients for their own problems, I shall cite the report of an out-patient upon his return from vacation. He had had a history of hospitalization for schizophrenia (his brother was recently hospitalized for the same problem). During his vacation, his wife walked out on him, leaving him alone in the motel. "I found myself sitting in bed the whole morning, and staring at my rigid finger," he said. "So I asked myself: 'Now what would Dr. Goldiamond say was the reason I was doing this?' He'd ask what consequences would ensue. And I'd say: 'Hospitalization.' And he'd say: 'That's right! Just keep it up and they'll take you away.' And then he'd say: 'But what would you be getting there that you're not getting now?' And I'd say: 'I'll be taken care of!' And he'd say: 'You're on target. But is there some way you can get this consequence without going to the hospital and having another hospitalization on your record?' And then I'd think a while and say: 'Hey! My sister. She's a motherly type, and she lives a hundred miles away.'" He reported that he dragged himself together, packed, and hitch-hiked to his sister who took him in with open arms. The education occurred in the process of analysis of several months of written records.

Noncoerced participation in programs specific
to coercive systems.

In a system using institutionally-instigated coercion, consent is suspect when it is obtained for participation in some program, research or

treatment, whose consequence is diminution of such coercion. Where there is institutionally-opportune coercion, the same precautions hold but, in this case as in the first, the social task is to define the amount and types of coercion we are willing to accept, and the protections against abuse we set up.

As was noted earlier, one solution is to separate programs from coerced consequences. In a prison, for example, diminution of coercion would not be contingent on research or academic or training programs, but other consequences might be attached. The congruent contingencies of the preceding section might be considered in this connection. The contingencies for noncoerced programs (outcomes and subject matter) in IIC systems would tend not to be specific to those systems, but concordant with those of the world outside.

There is, however, one type of program which is specific to the coercive system, rather than being concordant with the world outside, which might seriously be considered for both IIC and IOC systems. This is a program of research, treatment, or both whose maintaining outcome is nonrecidivism. Under appropriate precautions, such programs may be characterized by noncoercive mutuality of outcomes as well as by congruent contingencies for program-relevant behaviors of professionals and inmates/patients/students/research subjects.

In a prison system, a course of study which prisoners often readily enter into is how to avoid being sent up next time. The courses, of course, are informal and are taught by colleagues sub rosa. The non-recidivism at issue is defined by them as operationally as it is by any sociologist, namely, nonreturn. The social intent, or contingency, is in nonreturn reflecting nonrepetition of offense: the discharged prisoner goes forth and sins no more. The contingencies governing the

inmates may be otherwise: how to get away with it. Differences between operational definitions and operant contingencies notwithstanding, the popularity of the courses and their prevalence commends them to our attention as indicative of voluntary enrollment. Returning to the operant contingency permits the following suppositions. Suppose we try to develop (research/treatment) a program in the institution which trains complex repertoires and skills concordant with those on the outside. Suppose these would then provide consequences critical to the inmate. Suppose the skills are socially acceptable. Suppose enrollment in the program is not governed by consequences made critical by the institution, but by consequences concordant with those outside, as discussed earlier, and that enrollment here is one of several options available?

In a clinical situation, an analogous program, applicable as well to the world outside, would be a prevention or nonremission program.

In a mental hospital setting, Fairweather et al (1969), set up a research-treatment program whose subject/patients worked together in the institution to develop skills for each other which would maintain them in their own community-setting outside. A token economy was devised in conjunction with carefully articulated programs of increasing approach to such skills, in accord with p.i. Differences between these patients and controls with similar problems in socially-desired measures such as self-esteem while in the program and recidivism thereafter are striking. Keehn et al report related use of a token economy for alcoholics in a community of their own.

Consideration of the specific procedures used and their rationales is beyond the scope of this discussion. The issue is raised only in terms of its relevance for consent, coercion, and social contingencies. Many

types of responses can be established within institutional settings involving IIC and IOC. The maintaining consequences are often increased convenience for the staff, or demonstration of lawfulness for the investigator. That programing procedures can be applied to the investigation, development, and treatment of nonrecidivism for a variety of socially important contingencies, suggests the possibility of noncoerced participation in programs which typically utilize coercion, since their outcomes are specific to the coercive systems involved. These programs provide consequences for the individuals, the professionals, and the social systems which are important to each.

V. CONTRACTUAL RELATIONS

The social fiduciary model (f.m.) assumes inequality in powers. One party exercises its powers in the fulfillment of a trust for the protection of its wards, the other party. An alternative model is the social contractual model (c.m.) between two consenting parties assumed to be equally capable of consent. The powers are exercised in fulfillment of a future exchange for mutual benefit. What each party delivers the other in the exchange is explicitly stated.

It has been customary for practitioners and investigators to regard themselves as functioning within a f.m., and attentive to the welfare of those entrusted to their care. And if these professionals are hurt by or are indignant over what they interpret as an unjustified mistrust, they need but reflect on the steady public erosion in acceptance of the social f.m. (as distinguished from legal f.m.), and the steady substitution of social c.m. (as distinguished from legal or commercial c.m.). The change is reflected in relations between governments and citizens (formerly governed, or rulers and subjects), employers and employees, and husbands and wives, to mention but a few. Indeed, it would be surprising if

treatment or research escaped this trend. The slogan "Sit back and let us do the driving" may sit well in advertisements for a bus company, but it is being treated as skeptically when the practitioner states it in one form or another (trust us to decide for you; we'll keep our own house in order) as when government officials make such statements about their operations.

It is interesting to note that the Constitution in essence follows a model which tries to balance distrust of those in power with the necessities of effective exercise of power, and allows the federal government only those powers explicitly granted it. All nonspecified and residual powers are reserved to the (States and) people, the other socially contracting party. Elsewhere I have discussed the difficulties faced by mental illness professionals consequent on their substitution of a reversed model, in which the treatment system has all powers except those it grants its charges (Goldiamond, 1974). This model is contrary to the assumptions of the constitutional c.m., and is much closer to f.m. assumptions.

Each of the contracting parties is assumed to be equally capable of consent. My present concern will be with the equality relation. Capability will be considered in the next section. If there is to be equality, it might be reflected in equal specificity of the terms mutually agreed upon. However, contracts are often biased in specificity, imposing greater requirements for specificity upon one side rather than the other.

A familiar example of a contract where the burden of specificity is upon the client (payer) is the apartment lease. Here the responsibilities of the tenant are detailed so explicitly that they must be printed in small type in paragraph after paragraph. Aside from description of the premises provided by the agent (payee), provision of heat, access and other agent responsibilities are stated in general terms, which are kept to a minimum.

On the other hand, the burden of specificity is upon the agent (payee) in the consent forms for patients to sign before admission to hospitals or for procedures within them. What the hospital or staff might or might not do, that is, its responsibilities are often spelled out in such explicit detail that they require paragraph after paragraph of small type. What is required of patients is minimally explicit, and quite general.

While the burdens of detail imply a breakdown in trust-relations, differences in sidedness of the general-detail relations also imply the direction of whatever trust relation remains. In the hospital, the patients are to entrust the care of their persons to the professionals. For the apartment, the landlords are to entrust the care of their property to the tenants. However, patient-professional relations follow mainly from a f.m., whereas tenant-landlord relations follow mainly from a commercial c.m. Accordingly, trust is involved in both cases. Indeed, mutual obligations and responsibilities entered into the feudal f.m., even as faith and trust enter into commercial c.m. But the fact that I trust the manufacturer from whom I purchase my refrigerator to have exerted reasonable standards and precautions in its manufacture (with legal sanctions contingent on their violation) puts our relations no more on a f.m. than the mutual obligations of feudalism (with sanctions contingent on violation) put relations between noble and serf on a commercial c.m. Commercial c.m. are compatible with assumptions of trust and one does require a f.m. for a trust relation. We are loyal to certain stores and products and suspicious of certain professionals.

It is likely that the existence of elements of each model in the other derives from differences in social decision rules and other relations applied historically at different times, with the resultant present

situation representing different historical weaves. One outcome of the interaction of these weaves and changing modern conditions is that a fiduciary relation with which professionals felt comfortable and had worked from since the days of, say, Hippocrates, at least, is being interpreted as delegation of carte blanche powers to the professional. Accordingly, legal redress is being sought and other models are being applied. In this period of confusion, certain protections accorded to the individual by the social f.m. are being retained, while obligations upon the professional by the social c.m. are being added. It is probably in this context that statements by professionals that patients have obligations, too, are to be considered. Viewed in c.m. terms, a contract between an institution and individuals should not only spell out in detail what its obligations are (as is the present case), but would also spell out in equal details what the patient/subject obligations are (as is not the present case). If the field is moving to the social c.m., then the f.m. obligations should be changed to the explicit exchanges required by social c.m. Otherwise, both treatment and research delivery may suffer. Possibly this is necessary to preserve or produce a balance. Possibly the present division is considered as one-sidedly favoring the professional. Perhaps advancing technology is producing lop-sidedness in this direction, unless correctives are instituted. However necessary such corrections, if treatment and research delivery suffer, so too, will present and future patients, and the social system.

In all events, we might start making explicit what is involved and required. If a f.m. is to be retained, I am suggesting that this decision be treated as a decision, rather than as an article of faith or precedent. This would involve comparison of this option (retain f.m.) with at least one well-defined alternative (substitute c.m.), in addition to the other

explicit requirements of such analysis, including costs and benefits of each, and the decision rule we might follow.

Service and outcome contracts. Two types of social c.m. will be noted, a time/effort (service) c.m., and a specific outcome c.m.

In the time/effort c.m., the professional guarantees time and effort and the client pays for these. In return for payment, the practitioners guarantee neither recovery nor cure (occasion-outcome reversal) but simply that they will put in the time and skills necessary and paid for. The physician, teacher, and automobile mechanic are paid for time/effort by their patient, student, customer clients. This type of c.m. also applies to research grants. Here the granting agency pays and in return the university guarantees neither results nor contributions (occasion-outcome reversal), but simply that it will guarantee the time and skills of its principal investigator.

The time/effort c.m. of a research grant might serve as a model with which treatment c.m. are to be concordant. The client granting-agency, as was noted earlier, keeps track records of the accomplishments and previous awards of its principal investigator. The university and investigator keep similar records. The p.i. specifies procedures and rationale in detail, and the agency examines these with equal attention.

The patient, of course, is the client in clinical treatment. Lest it seem far-fetched to suggest that clients keep track-records of practitioners, at least one consumer group is now doing so in at least one branch of clinical treatment. Track records of different educational-treatment institutions for client-student use are available to potential students and, in some case, are prepared by professional educational associations themselves. Peer evaluation is thus made available to clients in education, as it is in grant review (the client is the agency), and this is not considered unprofessional.

The time/effort type of c.m. is generally used when outcomes are uncertain, or procedures have not been expressly validated. This is what research is about, of course, and this may underlie the confusion of experimentation with practice by practitioners. Where outcomes are more certain, where validated procedures are used, a different type of relation holds.

In the specific-outcome c.m., the professionals guarantee the delivery of outcomes or products which will meet explicit specifications. They are paid in return for this guarantee or performance. The research contract belongs in this category. In the educational treatment system, performance contracting has been tried, with mixed results. Here, the educational system is paid contingent on stipulated levels of performance by its students, following training. Since specific-outcome c.m. assume validated procedures, the procedures and delivery can be cost-accounted, and fees can be fixed. In health care, the "Blues" and other third-party payers often provide fixed-fee imbursement for specified procedures; this would appear to assume validation and certainty. It is of interest that in the field of psychotherapy, behavior modification is moving in such a direction. Its practitioners speak of imposing upon themselves requirements which generally do not characterize other branches of psychotherapy nor, for that matter, most other branches of treatment. These generally follow the grant model. It is of further interest that behavior modification contracts make explicit not only what the therapist does at each step, but what the client is required to do. Although most such contracts and records are explicit in terms of the chain-transactions of each of the parties in the interactions, with regard to payment, the fees at present are mostly for time and services. Accordingly, in most cases, the programs belong in the grant category, that is, the first one mentioned.

Contracts in which the agency is paid for time/effort ("professional services rendered") or for outcomes delivered have differing costs and benefits which are beyond the scope of the discussion (one of the major accusations against time/effort c.m. is that the delivery system, being reinforced for these, may maximize such reinforcement by increasing time rather than improving effort, which can better be accomplished through outcome contingent c.m. On the other hand, the system may then select its treatments in terms of payment, rather than actual service). However, the fact that the outcome c.m. ("research contract") seems appropriate where the "state of the environment" is known, and the time/effort c.m. ("research grant") where it is unknown, suggests the possibility of a decision model with shifting strategy criteria, depending on states of knowledge, outcomes, and decision rule to be followed.

Informed consent

The social contractual model assumes that two consenting parties are equally capable of consent, and have given it. Fulfillment of the contract is not binding on the party which is deficient in either.

Capability may be considered in terms of much of the preceding discussions, which will be summarized for this purpose. Degrees of coercion are defined by the number of genuine choices between alternative options, the critical nature of the consequences which govern the behaviors involved, and the conditions by which the consequences are made critical.

Degrees of coercion are inversely related to degrees of freedom, defined in terms of alternative well-defined sets of behaviors. Minimally, $df = 1$, that is, there are two equally available options.

Genuine choices involve such options when contingency repertoires are equal. Equality of contingency repertoires requires equally available opportunities or occasions, equally available patterns of behavior, equally

potent consequences and, since these are contingency repertoires and repertoires require establishment over time, equally functional contingency histories.

Critical consequences are those which are generally potent over others when made contingent on a particular individual's behavior, given certain broad sets of conditions.

Where, for genuine choices, $df = 0$, and critical consequences are attached to the option(s) and the consequences have been made critical by the system which provides them, coercion is then defined for that option, and no consent is meaningful. Where $df \geq 1$, and noncritical consequences are attached, consent is meaningful to the extent that it and the contingencies involved are concordant with those obtaining for similar options in the world outside. If research participation meets these conditions, it is acceptable.

Where, for genuine choices, $df = 0$, and critical consequences are attached to the option(s), and the consequences were not made critical by the system which provides them, consent must be examined critically, unless other arrangements discussed are provided. These include some of those holding in the preceding case, as well as those holding when mutuality of outcome is converted to mutuality of contingencies.

By and large, these define the conditions under which consent can be meaningfully obtained. They by and large define capability for consent.

What about the retarded, the illiterate, people who do not understand the language, and so on? Illiteracy and differences in language would seem to be governed by unequal-availability of occasions, which was discussed under genuineness of choice. There exists a more readily available guide which covers these cases as well as the retarded and other "incompetents". This derives from consideration of the social and

commercial c.m. If we apply the simple rule of concordance of acceptability of consent in the ordinary contractual case to the acceptability of consent in the c.m. governing individuals and patients, few special rules seem necessary. Consent to the terms of a car contract signed by imbeciles would not be binding on them, nor should consent to treatment or research contracts be binding on them. The professional who proceeds under the assumption of validity of consent will face the same problems in a court of law as a car salesman who proceeds likewise -- and will probably face problems more severe if the harm is greater. And the same holds for a person speaking a foreign language. Courts have defined other situations as well. Institutionalization in a mental hospital does not deprive mental patients of certain privileges and rights of citizenship, including freedom to enter into or decline certain programs. Whatever genuine surprise is engendered by judicial opinions which question treatment/research consent under such conditions is probably derived from the fact that the professionals are not attuned to the applicability of contractual arrangements to their bailiwicks, rather than from their ignorance of the contractual relations involved. They encounter these daily as members of a complex commercial-industrial society.

It would seem that attention to concordance with conventional contractual relations obtaining outside would eliminate at least some of the confusion surrounding the area. Whether the contracts are for time/effort or for outcome, the requirements on each party might be stated explicitly, as they often are outside. Where the issue is disclosure of data obtained during treatment or research, for research publication or for didactic presentation to improve treatment, and there is possibility of damage

through identification, or invasion of privacy, or in other ways, the tort law prevailing on the outside, for damages unrelated to contractual fulfillment, might be considered. Or where contracted disclosure was violated, the breach of contract model might be considered.

It is probable that the laws and social arrangements are changing in these areas, even as the social contingencies they reflect are changing. Time-honored models whose definitions are implicit rather than explicit (e.g., intent and fiduciary models) make related social policies subject to varying interpretations and therefore to abuse by those in power who are so inclined. These models are gradually being joined by more explicit models, and the resultant confusion provides no fixed guides. In such cases, solutions to problems in the area of patient-subject protection may provide precedents and help provide solutions for a society that needs all the help it can get.

In the meantime, we might profit from its past efforts and solutions. But this interchange can best be facilitated if the models applied to our areas of concern are consonant with those the rest of the social order is finding to be of increasing applicability. And these models include the contributions of the scientific systems of consequential contingency analysis found in behavior analysis, transactional analysis, exchange theory, decision theory and cost-benefit analysis; the contributions of the legal systems faced with requirements for explicitness; and the contributions of the larger and equally explicit social contractual models they all reflect.

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15

BOUNDARIES BETWEEN RESEARCH AND THERAPY,
ESPECIALLY IN MENTAL HEALTH

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and

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Boundaries Between Research and Therapy, Especially in Mental Health:

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Terminology and Scope of Treatments

There is no universally accepted terminology covering the many kinds of treatment used in the field of mental health. The vast majority of such treatments, however, consist more or less completely of some kind of verbal dialogue between the person administering the treatment and the person who receives it. This is true of virtually all treatments which go under the titles of counseling, case work, insight therapy (including psychoanalysis in most of its forms and variants, and client-centered or non-directive therapy), psychiatric or psychological interviews or consultations, encounter groups, humanistic or existential therapy, Rational-Emotive Therapy, Transactional Analysis, and most forms of group psychotherapy and behavior therapy.

A second order of psychotherapeutic activity also uses verbal interactions as the main instrument of treatment, but in more dramatic or unusual forms than that of conventional conversation, and often combined with specific behavioral methods of rehearsal or with altered states of consciousness. Included in this category are Psychodrama,

Gestalt Therapy, Assertion Training, Relaxation Training, Sex Therapy, Desensitization, Implosive Therapy, Behavior Shaping or Operant Conditioning, and Hypnosis.

Finally, a third class of mental therapy makes active use of equipment or of physical manipulation of the body by variations of massage. Included here are Aversion Therapies, Biofeedback, Bioenergetic Therapy, and Rolfing. The psychotherapeutic use of tranquilizing, energizing, antidepressant, and other psychotropic drugs is also, logically, in this class of treatments, as is electro-convulsive therapy (ECT). In fact, there are some forms of aversion therapy which use drugs as the active agent for producing aversive responses, such as the treatment of alcoholism by Antabuse, and the combination of psychotropic drugs with verbal and other psychotherapeutic methods is increasingly common and very promising. Since the use of psychotropic drugs is already regulated by the FDA, however, it is not included in this discussion. Most aversion therapy uses mild electric shock as the repulsive agent, and this usage is not currently regulated.

It should be noted, moreover, in discussions of this class of treatment, that Biofeedback, despite its use of often very sophisticated physiological recording equipment, is not strictly comparable to the other treatments which involve very specific manipulations of the body, either by inducing physical discomfort (aversion therapy) or by massage (bioenergetics, rolfing). Biofeedback equipment simply records ongoing physiological processes and then gives the patient information about them

in the form of auditory, visual, or tactile signals. The patient can then learn to alter the body processes by learning how to manipulate the sensory signals. Taking one's own pulse or observing one's own breathing are literally forms of biofeedback. The therapeutic use of this technology, despite the equipment involved, may actually be more closely related to some simple forms of Behavior Therapy, such as Relaxation Training, than to treatments which manipulate the body. I have included it in this class only because most biofeedback treatment involves the attachment of electrodes to the body connecting it to complex machinery, which gives the whole thing an aura of scientific quality which can easily mislead patients, research subjects, and legislators into thinking it is either more dangerous or more effective than is necessarily the case.

The listing above does not include all the named forms of mental health treatments by a long shot. Estimates vary up to 130 or more names. It does, however, include representatives of every kind of mental therapy used by psychiatrists, psychologists, social workers, nurses, counselors, and all those professionals and paraprofessionals who claim expertise in this domain except neurosurgeons, whose work is not discussed here. Since there is no single term which adequately covers the field, moreover, I shall use the terms "mental treatment" (or "therapy"), "psychological treatment" (or "therapy"), and "psychotherapy"

interchangeably to refer to all treatment methods and classes in the entire field of mental health, except where specified otherwise.

Distinguishing Research from Therapy

Intent

From the perspective of protecting subjects, the first thing that distinguishes research from therapy is the intent of the subject. So the first mandate of the researcher is to explicate to the subject whether, and to what degree, the manipulations involved are aimed at getting knowledge, independent of whether they will help the person. You don't need to place the same burden on the therapist, since therapists' and subjects' aim always coincide anyhow -- that is, the reasonable presumption is, when someone goes to the doctor, that they are going for some benefit to themselves, not for the primary purpose of benefitting the doctor by giving him information.

The biggest problem arises when the intent of the subject is primarily to get help and the intentions of the therapist are mixed either by a compound of scientific and therapeutic motives or by the fact that the only treatments available are experimental, that is, new enough or controversial enough so that their suitability for the given case is doubtful. The latter case, of innovative or experimental treatments, subsumes the case of mixed therapist motives. The problem, in turn, reduces to: 'When should we define a therapeutic activity as being

research, regardless of the declared intentions of patient or therapist to label it 'treatment'?"

For the purposes of the Commission, this says, establishing the boundaries between research and the routine and accepted practice of mental therapies does not require the definition of research, but only the definition of therapy, because we are saying that anything which purports to be therapy and is not routine and accepted as such, is automatically research.

The issue of therapist or investigator intent is not logically important for our purposes. If someone intends that his work should be considered research, it is research, in terms of needing safeguards for protecting subjects, regardless of whether its methods are intended to be therapeutic. But not all that is intended to be therapy, is therapy, for these purposes. This means, in effect, that we do not need to define research at all. We can attack the problem of boundaries meaningfully by recognizing that the practical problem is that many therapeutic methods are well intended, but poorly established (in terms of safety, efficacy, and economy). One cannot demonstrate the efficacy of a therapy in terms of the intentions of its proponents, because nice guys, in addition to finishing last, may propose ineffective treatments. And they may even propose harmful therapies with the best of intentions. No more can a therapy be considered routine and acceptable on the basis of authority. Only evidence will do.

Peripheral Problems

Once it is clear that the central problem of boundaries can be settled adequately by limiting our inquiry to the definition of therapy and the assessment of routine and accepted practice within that definition, several problems which may be important in other contexts become peripheral here and may be dismissed from this discussion:

Who pays whom, who asks for help from whom, whether the primary goal is the accumulation of knowledge rather than the assistance of an individual, is there a research protocol, all become irrelevant questions for our purposes. Nor is there any need to distinguish here between "research" and "experimentation", or to separate either of them from "experimental" or "innovative" therapy. Dictionary aside, from the vantage of protecting subjects, they are all the same.

Distinguishing Mental Health from Other Medicine

The problem of "accepted and routine practice" in the field of mental health differs somewhat from the same problem in other fields of medicine for three reasons: 1) The number and variety of nonmedical people, in and out of the learned professions, who have legitimate input into this field is considerably greater than is true in any other branch of medicine. So routine and accepted practice cannot, in most respects, lean on the specific training, licensure, or certification of the practitioner to help define the behavior in question. 2) The specific

practices which can be defined as therapeutic overlap so much with equally valid definitions of them as educational, recreational, or religious, that it is presumptuous and impractical to try to restrict these practices completely to medical or therapeutic functions or functionaries. 3) The goals for which mental therapies, however defined, are sought, and the sensible criteria for deciding whether they have been achieved, are so diverse that they cannot all be contained within any definition of health short of the WHO definition, and that definition is too broad for legislative use.

If these problems are recognized at the outset, it may then be reasonable to seek boundaries between therapy and research in the many contexts where the distinction between them can be meaningfully designed to protect the subjects of research, without trying to comprehend and include every context in which such distinctions are possible. The development of meaningful regulations in this connection might not, for instance, seek to restrict a church from conducting Transactional Analysis meetings for its members, even were it clear that the procedures involved are technically considered innovative or experimental therapy.

A more immediate illustration, perhaps, is Institutional Review Boards, which automatically review anything that purports to be research. The question for them is: what things should they review that claim to be therapy, or that do not claim to be research? Evidently, they would have to review all training and demonstration grant proposals in which

the procedures to be taught or shown fall outside the scope of "routine and accepted practice". To do so, however, they would have to have therapeutic guidelines. At the present time, the only such things in the field of mental health are FDA guides for the use of drugs. There are no equivalents for psychotherapy or counseling. Without them, any IRB whose members were very knowledgeable about the state of the art in psychotherapy would find themselves hamstrung. The need for such guidelines, as we shall see, seems virtually inescapable if the protection of human subjects in this domain is to be meaningfully regulated.

Outcome Criteria

The problem of deciding when a therapy, treatment or training program has been sufficiently tested so that it is no longer experimental is, on the face of it, the same as the problem of when a drug achieves the status of acceptability, so that it no longer has to be considered experimental. By and large, the things at issue are safety, efficacy, and economy. In the case of therapy in the field of mental health, economy may be subsumed under efficacy because one of the most important criteria of acceptability in psychotherapeutic kinds of treatment is the length of time and amount of effort it takes for a treatment to work in comparison to other treatments and in comparison to nontreatment conditions.

The problems of safety and efficacy in mental treatments are not

necessarily the same as with drugs -- in general, efficacy is a bigger problem, safety a smaller one, and both more complicated. Both issues are joined as the problem of outcome criteria, which has plagued the field of mental health since the advent of modern psychotherapy.

That problem, stated briefly, is:

What are the goals of psychological treatment?

How can we tell whether they are being met?

What dangers attend the treatment process?

In the early history of psychotherapy, the goals of treatment tended to be clear. They were the relief of specific symptoms of neurosis, such as phobias and other anxiety states, the repair of hysterical conversion reactions, such as hysterical blindness or paralysis, or of dissociative states, such as amnesia, the relief of disabling obsessional thought patterns and compulsive rituals, and the restoration of good feeling in people incapacitated by depression. Insofar as such specific symptomatology is to be found in people who are given psychotherapy, relatively efficient outcome criteria can be established, because the clear definition of the problem permits a fairly clear determination of whether or not it has been relieved. A large proportion of neurotic and psychophysiological conditions are of this kind.

Safety. Since the end of World War II, however, and more pronouncedly since the 1960's, when encounter groups became very popular through the offices of humanistic psychologists and the "human potential movement,"

more and more psychotherapeutic activity has been undertaken for nonspecific conditions, where the people requesting treatment would not admit to specific problems of the kind contained in conventional psychiatric nomenclature. Some of these conditions were represented as general malaise, disaffection with one's circumstances, or unhappiness, that is, as existential problems which might properly lie completely outside the purview of mental health, in its technical sense. Others were represented as recreational, educational, or quasi-religious, that is, as the desire of people who were not only free of symptoms, but were even happy with their lives, to have therapy as a "positive growth experience" which, on the face of it, is even further removed from the domain of mental health technology. These conditions are matters of concern here because, while the definition of the problems in such cases, places them outside the arena of mental health, the methods which are applied to those problems may be potentially harmful to some of the people they are used on.

The recreational or educational character of psychotherapy is comparable, in this respect, to elective cosmetic surgery. Your intention, in getting a "nose job," may be to get more beautiful, rather than to get healthier -- but the surgeon's knife will do just as much damage one way as the other, if it slips. In fact, many of the "awareness enhancing" methods of the human potential movement were specifically developed as psychological treatments and were published

under the authorship of trained and licensed mental health practitioners. It would be specious to view them as anything other than mental therapies. This definition of the method may necessitate that some such treatments have to be regulated under the outcome criterion of safety, even if the nonspecific character of the "problem" makes the positive efficacy of the treatment method irrelevant. In practice, this could mean that encounter groups of the kind run at "growth centers" such as Esalen, or Arica, or EST (Erhard Seminar Training), might all be subject to scrutiny as innovative or experimental psychotherapies, even though they do not claim to be mental health treatments and even though their customers do not claim to need or want mental health treatment.

As if the foregoing were not complicated enough, from the vantage of practical regulatory measures, the very same logic might apply equally well to the increasing deliberate application of behavior modification principles to routine classroom teaching problems, such as the improvement of reading or arithmetic skills; and it could also apply to self improvement programs such as Weight Watchers, which increasingly makes deliberate use of behavior modification to help people control obesity. Indeed, applying the safety criterion to the methods in question may necessitate just such scrutiny, regardless of where those methods are to be used.

The judicious application of the safety criterion would probably exempt both Weight Watchers and arithmetic teachers from regulation,

however, because enough research already exists predictably to show that the application of the behavior modification principles involved has very low probability of doing any specifiable damage to any arithmetic student or obese person under almost any circumstances. Existing research would be less likely to exempt encounter groups or EST, however, and the establishment of reasonable guidelines would not be easy for deciding "how safe is safe", that is, how much of what kind of harm is "allowable" to what percentage of people who undergo that "treatment".

In principle, the safety problem with psychotherapy is the same as with drugs. But in practice, it is more complex and less ominous at the same time. Few people, if any, die from psychotherapy, or get grossly incapacitated, and the few who do, tend to do so by such slow stages that reasonable observers might attribute the damage to other circumstances than the treatment. Even so, some people are harmed by psychotherapy, and more potentially can be harmed as mental treatments become more efficient, which they will -- so the need to regulate the protection of research subjects must logically include the implementation of some means for regulating the safety of innovative mental therapies, however complex the problem is. Drugs undoubtedly kill and injure more people, but the determination of their safety is aided significantly by the fact that the damage they do tends to be more specific, more dramatic, and sometimes visible on other animals than human beings. The

safety of psychotherapies is a more complex problem of definition and of empirical determination -- therefore, it is also a more complex problem of regulation.

Efficacy is a bigger problem than safety in mental health treatments, because their downside risk is more likely that of being harmless and useless than of being very potent in either a beneficial or dangerous direction. Even so, the means by which efficacy is established for psychological treatment of all kinds is, in principle, essentially the same as the means by which effective outcomes are determined in any other domain -- by empirical assessment of the relative precision with which a given technique achieves a predetermined result in comparison with all other conditions under which the same result is or is not achieved. The foregoing proposition states, in clumsier than usual language, the principle by which the syllogistic determination of cause and effect (If a, then b; if not b, then not a) is applied to all scientific problems. Translated into the specifics of mental health, it says:

A psychological treatment is effective if it achieves its specified goals. The faster it achieves them, and the more people it achieves them on, and the more thoroughly it works on those people, the more effective it is. The comparisons involved are comparisons of the treatment in question to other possible treatments, including no treatment at all.

The specifics of the kinds of cost-benefit analyses which would go

into the actual assessment of any given therapy are somewhat variable, but there is no need to pursue them in detail in this essay because the principles involved are well known and unequivocal: They are the fundamental principles governing all scientific investigation -- measurability and replicability. For a therapy to meet the efficacy criterion, it must be measurably better than other treatments and than nontreatment by standards which permit independent observers, using the same methods he did, to disconfirm the results of the original investigator. When others have tried, and failed to disconfirm, then the efficacy of the treatment is established. Until then, it is not.

This notion of efficacy has two important implications for the purposes of the Commission:

1) With respect to mental health problems, it allows for the legitimacy of idiosyncratic, unconventional definitions of treatment, or improvement, or cure, provided only that those definitions can be subjected to the same empirical evaluation procedures as any others. This makes it possible, for instance, for Thomas Szasz to argue that the notion of mental illness is a banal fiction and still to propose treatment models which can be validated as effective mental health instruments. It separates the empirical problems of treatment from the theoretical problems of defining the discipline.

2) It implies that the boundaries between research and practice may, for practical purposes, be established without concern for the intent

of the investigator or practitioner, if not the patient. If treatment efficacy is established only when repeated investigation by conventional scientific rules has failed to disconfirm a treatment's relative efficacy, and "routine and accepted practice" is routine and accepted because the treatments involved are effective, then the boundary between research and practice is the degree to which the knowledge of efficacy exists. That knowledge is a complex, but inevitable function of the extent to which the relevant research has already been done and replicated, not of the intentions of the particular scientist or therapist.

In its most general sense, research means trying to find out something that you don't know, which makes intent seem critical. But from the vantage of social regulation, and from that of the scientific community, the definition of a research problem is not what you know about something, but what is known about it. From their personal perspectives, little boys and girls poking around each other in the bushes are doing research on where babies come from. But from the vantage of the community, the question is not a proper subject of scientific research because the answer is already well known.¹ By the same token, the definition of routine and accepted therapeutic practice, in any domain which is subject to scientific inquiry, depends on the extent to which the relevant scientific questions have already been answered. The more they have been answered, the more

¹ The stork brings them.

a given form of practice is routine and accepted. The less they have been answered, that is, the more the questions of efficacy are open to scientific inquiry, the more a given form of practice becomes research, no matter what the intentions of the practitioner may be. The size and quality of the body of inquiry addressed to those questions and the size and quality of the body of knowledge it has produced index the permeability of the boundary between the two. In the complex variable systems of the biomedical and behavioral sciences, far more than in the physical sciences and their applications, the assessment of that boundary is a matter for negotiation. For practical purposes, this means that the determination of the boundary requires continuous, conscientious, and sophisticated scrutiny, assessment, and reassessment of the scientific status of the treatment arts.

Guidelines for Guidelines

The detailed means for best conducting that assessment are not obvious, nor is the process of expert negotiation and consensus which will best summarize and judge the scientific status of each mental therapy, disseminate the information in the form of guidelines for review boards and funding agencies, and assure the proper revision of those guidelines as new knowledge accrues and old biases surface. Perhaps a new office should be created within HEW for this purpose, and perhaps it could derive some guidelines for creating guidelines from the practices now used by the Food and Drug Administration for evaluating drugs and by NIH for

evaluating research grant proposals. There are some special problems connected with evaluating psychological treatments that may require some thoughtful innovation in regulations and bureaucratic procedures -- the unreliability of psychiatric diagnoses, for instance, makes it harder to be sure you have met your intended outcome criteria in any given research study than would otherwise be true, even if the specific results of this study are significant statistically. Additionally, there are often large variations in therapeutic procedures of a single kind, depending on personal qualities of the therapist unrelated to professional training or competence, which might further confound the interpretation of results from one experiment to another, even where the subject selection criteria in both studies have been reliably the same. And such vagaries, among others, make the assorted biases of the people doing the evaluation and review much more influential, potentially, in their judgments of mental health treatments than might be true if they were evaluating drugs. And there are still other special problems.

What does seem obvious, in any case, and despite the problems involved, is that there cannot be any meaningful protection of research subjects in the field of mental health research unless there is regulation of innovative, experimental, research-demanding mental health treatments. The classification of treatments in that box, separating them from routine and accepted practice, requires, in turn, the preparation of objective guidelines based on comprehensive, fair minded evaluation of empirical evidence, and routinely revised as new reasoning and new discovery dictate.

LEGAL IMPLICATIONS OF THE BOUNDARIES BETWEEN BIOMEDICAL
RESEARCH INVOLVING HUMAN SUBJECTS AND THE
ACCEPTED OR ROUTINE PRACTICE OF MEDICINE

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This paper discusses the legal implications of physician activities that occur on the boundary between research and the accepted practice of medicine. After showing that no major legal consequences turn on the characterization of an activity as research or practice, the paper then discusses whether legal consequences should attach to the distinction, concluding with a general discussion of policy alternatives for innovative therapy.

Boundary activities* require consideration in developing public policy for research with human subjects ^{1/} because they subject patients under the guise of therapy to risky, untested procedures without the safeguards that apply to experimentation. The problem arises because physicians often undertake diagnostic or therapeutic procedures about which little is known and which deviate substantially from routine, accepted practice. This may occur because there is no known effective cure and the physician seeks a procedure helpful to the patient, or because the new procedure appears to be superior in cost, efficacy, or side-effects to the standard procedure. Because data establishing efficacy may be lacking, its use may be said to be experimental. The concern here is that untested therapies will be used without controlled clinical trials to the detriment of patients, and may even come to be accepted as standard therapy, when later experience shows that they are actually inefficacious or harmful.

Current HEW policy views such activities as placing a subject at risk and hence subject to IRB review because they "depart from the application of those established and accepted methods necessary to meet his needs." ^{2/} In addition, whatever the physician's specific intent in

*In this paper the terms "boundary activity" and "innovative therapy" are used as synonyms.

employing the new procedure, the consequences are likely to resemble the consequences of activities done with a specific intent to do research. The application of an innovative therapy will often yield knowledge that affects treatment of future patients in the same situation. Also, experience with one or several patients may lead to publication, and thus for the physician approximate the consequences of the research enterprise.

At the same time, however, treatment of all boundary activities as research poses conceptual and policy problems because an experimental intent may be lacking. The physician using an innovative therapy may have no research or experimental aims beyond helping his patient. If asked, he will say that he is engaged in therapy only, and intends only to treat this patient rather than conduct research beyond that involved in any diagnosis or therapy. Moreover, a public policy that treats all boundary activities as research will implicate the government in physician practices far beyond those directly funded by HEW or occurring in HEW funded institutions, ^{3/} and will intrude into the doctor-patient relationship far beyond current regulation. ^{4/}

The question to be addressed is what safeguards, if any, beyond those applying to ordinary medical practice are needed when a physician, through application of an unaccepted or untested procedure, attempts to confer a therapeutic benefit on a patient. Is every intentional departure from accepted practice to be considered research and subject to controls for research? Or can some instances of innovative therapy be distinguished from research and be treated separately? The answer lies in an examination of the risks created by boundary activities, the efficacy of current controls, and the incremental costs and benefits of additional controls, such as those applied to federally

funded research. To illuminate these issues this paper first analyzes the legal implications of characterizing a medical activity as research or therapy and then considers the policy alternatives that follow from these implications.

1. LEGAL CONSEQUENCES OF CHARACTERIZING MEDICAL ACTIVITY AS RESEARCH OR PRACTICE.

While characterization as research or practice may ultimately have policy significance, at the present time it is reasonably clear that the labelling of a medical activity as research or practice has no major legal consequences in terms of who may engage in the activity, the circumstances under which a negligence award will be made, or the amount of information that must be disclosed to the subject of the activity. In the context of therapeutic activity that includes elements of research or innovation, no question of who may perform therapy or research arises, for we can assume that activities of physicians and other appropriately licensed health professionals are involved. Moreover, there are no specific criminal prohibitions on doing research which legally distinguish research from therapy. The major points of difference, if any, concern liability and disclosure rules.

A. Tort Liability

Aside from licensing and medical practice acts that restrict the persons who may practice medicine, and the general provisions of the criminal law, the primary legal constraint on physician activity arise

from the after-the-fact review and damage awards of the tort system. While conceivably different standards for ascertaining liability and imposing damages could apply, there appears to be no major difference between therapy and research in the standard for finding liability.

1. Liability for Accepted or Routine Practice

A physician will be liable for damages if he fails to possess a reasonable degree of skill and to exercise this skill with ordinary care and diligence. What is reasonable and prudent care is usually determined by the practice of other physicians in the same or similar circumstances, ^{5/} though on occasion the courts have required a standard of care higher than that of professional practice. ^{6/} In general, then, a physician will incur no liability for use of a procedure, test or technique if he uses it in a nonnegligent way (that is, as carefully as other physicians in those circumstances), and it is considered by at least a respectable minority of physicians to be an accepted therapy in the patient's situation.

2. Liability for Experimentation and Innovation

While the earliest American cases involving medical experimentation or innovation seem to indicate that a physician will be strictly liable for any deviation from standard or accepted practice, even if done for the purpose of developing a better therapy, ^{7/} there is now considerable support for the proposition that liability for innovation depends on the reasonableness of the use of an innovative procedure in the circumstances of the patient. ^{8/} The reasonableness of deviation from the accepted or routine therapy will depend on the predicted condition of the patient, the probability of success of customary therapies, the probability of success

of the innovative procedure, and the probability, type, and severity of risks collateral to the therapy. The innovative departure will be reasonable if it reasonably appears that the chances of providing a benefit to the patient beyond that of customary therapy outweighs the likely risks of the innovation. As with a standard therapy, the question of liability depends on reasonableness of use:

It does not follow from the fact that a method of treatment is innovative that it is not reasonable medical practice to use it. Expert testimony on this issue can evaluate the defendant physician's innovative therapy on the basis of the condition of the patient, the probability of success of the therapy, and the nature, severity, and the probability of collateral risks. Such expert testimony would be responsive to the fundamental and long-familiar inquiry: Did the defendant doctor conform to the standard of care of a reasonable practitioner under the circumstances confronting him. 9/

Although the liability rule is identical for activities characterized as accepted or innovative therapy, the factual inquiry occurring in each case will differ. In an action for damages arising from use of an accepted therapy, the factual inquiry will usually concern establishing standard practice, and proving that the physician in fact deviated from it without justification, that is, administered or performed the therapy in a negligent manner. With an innovative therapy, the factual inquiry will also concern establishing the accepted therapy, but then focus on the justification for departure from it: what was known of the innovative procedure, the likelihood of risks, and the grounds for thinking that it would bring the patient a net benefit beyond that available with the accepted therapy. In this inquiry particular attention is likely to be

paid to the physician's consideration or use of customary therapies, the amount and type of prior investigation with regard to the innovative procedure, the results of animal research, if any, the conclusions that one can draw from general scientific principles, what the physician knew or should have known of those risks, and, in short, whether a reasonable practitioner, in the circumstances as established, would have been willing to undergo those risks to obtain the expected benefits. Thus, in the ordinary malpractice case the question of reasonableness usually will depend on whether the physician conformed to or deviated from the accepted standard of care. With innovative therapy, the question of departure is conceded and the question of reasonableness concerns whether the departure is justified given the patients prospects without it and the likelihood of a net benefit with it.

A possible legal consequence could turn on the characterization of a boundary procedure as research or therapy, if research activities generally occurred only with the prior approval of an Institutional Review Board (IRB), as is now the practice for HEW funded research and, in many instances, for all research occurring in institutions receiving HEW funds. ^{10/} Two possible legal consequences could turn on this practice: (1) immunity from liability if the IRB approves the activity and legally effective consent is obtained; (2) imposition of liability where IRB approval is not obtained.

With regard to the first question, IRB approval alone would not provide immunity in a suit based on negligence in undertaking the innova-

tive procedure, even if the procedure were nonnegligently performed, and legally effective consent were obtained. The claim here would be that it was tortious to undertake the procedure at all, even with full consent, and its legal resolution would depend upon the reasonableness of the experimental procedure - that is, whether the likely benefits to the patient - outweighed the risks. Although relevant and possibly persuasive, IRB approval alone would not determine the reasonableness of the activity. The IRB could have acted negligently or misjudged the risk-benefit ratio, and in any event, has no legal power to foreclose a court from independently determining reasonableness. In fact, the IRB's standard of reasonableness (do the sum of benefits to the subject and increase in knowledge outweigh the risks to the subject), 11/ which take account of benefits to others, may well diverge from the standard applied by the courts. A persuasive argument, based on the law's concern with personal integrity, can be made that the courts should and would exclude nonsubject benefits in this calculus, and would view the risk-benefit ratio solely from the subject's perspective. Thus, while prior IRB review may be helpful in screening out "unreasonable" research, it is no guarantee that liability will not attach to procedures that it approves.

Conversely, failure to obtain or the denial of IRB approval may be relevant and even persuasive evidence on the question of the unreasonableness of undertaking a research activity that occurred with legally valid consent, but again it is not determinative. The reasonableness of the procedure depends on the risks and benefits to the subject. Analytically, IRB review does not alter the risk-benefit ratio of the proposed procedure, 11a/

If the physician could establish that an activity characterized as research were reasonable in the circumstances, lack of IRB approval alone should not lead to liability.

An exception to this conclusion could occur if IRB review were mandated by statute. ^{12/} In that situation a court could find that violation of the statute was negligent per se, because the statute was designed to protect the class of persons in which the plaintiff is included, against the risk of the type of harm which has in fact occurred as a result of its violation. ^{13/} However, there would still remain open such questions as the causal relation between the violation and the harm to the plaintiff, ^{14/} and possibly such defenses as assumption of the risk. ^{15/} The plaintiff would still have to establish that IRB review in this instance would have prevented the activity, either because it would have found the risk-benefit ratio unfavorable or would have required a fuller disclosure that would have occurred, which in turn would have led to nonsubject participation. If the risk-benefit ratio were in fact reasonable and legally valid consent obtained, it would be difficult to show that IRB review would have prevented the activity. If the risk-benefit ratio were unreasonable, or the consent was invalid, liability would exist independent of IRB review. Even if it did not, the plaintiff would still have to show that IRB review would have prevented the injury, possibly a difficult task with the current lack of empirical data on IRB effectiveness in preventing harmful research or actually improving consent procedures. ^{16/}

B. Consent and Disclosure Requirements

In addition to rules imposing damages for untoward results where a physician unreasonably deviates from the standard of care, another major legal constraint on medical activities are rules requiring physicians to disclose certain information about a proposed procedure for a patient's consent to be deemed effective. Technically part of tort liability, consent is sufficiently important to warrant separate consideration. However, analysis again reveals that with one possible exception disclosure rules do not vary with the characterization of a boundary activity as therapy or research.

1. Disclosure In Accepted or Routine Practice

Generally, a physician may not treat a patient without consent.^{17/}

In determining the effectiveness of a patient's consent, the question arises of how much information concerning the proposed procedure must be disclosed in order for the patient's consent to be valid. Traditionally, the rule has depended on the customary disclosure practice of the profession for the given situation. Generally, the plaintiff has the:^{18/}

burden to prove by expert medical evidence what a reasonable medical practitioner of the same school and same or similar community under the same or similar circumstances would have disclosed to his patient about the risks incident to a proposed diagnosis or treatment, that the physician departed from that standard, causation, and damages.

Recently, with Canterbury v. Spence ^{19/} and a subsequent line of cases, ^{20/} a minority of jurisdictions have begun to apply a new disclosure rule, based not on professional practice, but on the amount of

information which a reasonable person in the patient's circumstances would want to know in deciding to undergo the treatment: 21/

(T)he standard . . . is conduct which is reasonable in the circumstances . . . the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risk potentially affecting the decision must be unmasked. The topics importantly demanding a communication of information are the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated. The factors contributing significance to the dangerousness of a medical technique are, of course, the incidence of injury and the degree of harm threatened.

In sum, liability for nondisclosure of the risks and other material details of accepted or routine care will depend on the jurisdiction in which the nondisclosure occurs. In either case the plaintiff has the burden of establishing the information required to be disclosed under either the professional practice or reasonable person standard, that such information was not disclosed, and that had disclosure occurred, the plaintiff would not have undergone the therapy.

2. Disclosure in Research and Experimentation

While there are few precedents concerning disclosure requirements for research or experimental procedures as such, and cases in two jurisdictions suggest that the experimental or innovative nature of a procedure should always be disclosed, 22/ it appears that the disclosure rule for accepted therapy would also apply to innovative or experimental procedures. Thus in a jurisdiction requiring conformity to professional custom, the experi-

mental or innovative nature of the procedure, its specific risks and benefits, and the risks and benefits of alternative procedures would be disclosed only if the custom or practice of physicians in that situation was to disclose such information. A precise answer to the question what must be disclosed would thus depend on an empirical inquiry with regard to each use of innovative therapy, and whether a local, similar community, or national custom of practice were applied. Presumably, at least in some instances, medical practice could include as full or even greater disclosure than occurs under the Canterbury reasonable person disclosure standard, but this would vary with the procedure and the particular circumstances of its use.

In a Canterbury-type jurisdiction the fact that a procedure is innovative or therapeutic, its risks and benefits, and the risks and benefits of alternative procedures, would be disclosed only if a jury or court in its after-the-fact review concluded that such information would be material to the decision of a reasonable person in the patient's circumstances whether to undergo the procedure. Arguably such data would be disclosed under this standard, though the courts have not yet directly confronted whether the innovative nature of a procedure must also be disclosed. ^{23/}

Elements of consent required by HEW ^{24/} for research which it directly funds would probably have little impact on disclosure requirements in a Canterbury-type jurisdiction, since those elements would appear material to a patient's decision to consent and hence legally required. However, they could be persuasive evidence of professional practice regarding disclosure in jurisdictions requiring disclosure in conformity with

professional custom. Despite some ambiguity, the HEW regulations appear to require the IRB to assure that consent will not only be legally effective, ^{25/} but also will be "informed," which is defined ^{26/} to include disclosures that would clearly go beyond professional custom disclosures, specifically the fact that the procedure is experimental, as well as disclosure of discomforts, risks and benefits of the procedure, and alternatives. ^{27/} Assuming in a professional custom jurisdiction that the HEW consent rules were generally followed by the profession for all research, a court could find that the HEW disclosure requirements defined the professional custom and hence the disclosure rule for experimentation. If that were the case, then in a professional custom jurisdiction characterization of a procedure as experimental could have legal significance with regard to liability for nondisclosure. But such a conclusion would depend on showing that the procedure in question was in fact experimental, and that a custom of submitting all experimental procedures, whatever their funding source, to IRB review, existed. If, as is more likely, the custom could be established only for research directly funded by HEW or occurring in HEW funded institutions, then the HEW disclosure standard would not apply to all innovative procedures occurring in that jurisdiction. Thus, while a more stringent disclosure requirement for research might exist in a professional custom jurisdiction, this standard would most likely apply only to research in HEW funded institutions, and only then if a court accepted this argument.

11. The Need for Special Protection in Boundary Activities

Since experimentation is not a legal category with separate liability and disclosure rules, there are presently no significant legal consequences that hinge on a boundary activity being characterized as research or therapy except for a possibly more stringent disclosure requirement in certain circumstances. Moreover, even if research or experimentation had legal significance as such, legal consequences beyond those applicable to ordinary therapy would attach to boundary activities only if they were always regarded as research. As discussed below, there are sound reasons for not treating every application of innovative therapy as research.

The question remains whether legal significance should attach to boundary activities, no matter how they are characterized. This could result from creating special rules for experimentation, and treating some or all boundary activities as research. Or rules more stringent than for accepted therapies and less restrictive than for research^{28/} could be legislatively or administratively devised to regulate boundary activities. Alternatives here include criminal prohibitions, disclosure and liability rules, and prior or after the fact review. Before considering such alternatives, however, it is necessary to consider whether boundary activities (1) create risks to patients beyond those of ordinary medical practice, and, if so, (2) whether existing legal and peer review mechanisms provide patients sufficient protection. If risks to patients greater than the risks of accepted practice exist, and they are not sufficiently

controlled by existing mechanisms, then consideration should be given to alternative techniques for controlling them.

A. The Problem of Innovative Therapy: The Risks

An important issue is whether boundary activities, which share features of ordinary practice and innovation, create risks to the patient beyond those that exist in the application of accepted, routine therapies. If so, are those risks so similar to the risks of physician conflict and loyal future patients existing in pure research that they require similar treatment? Boundary activity or innovative therapy may create additional risks in at least three ways.

First, simply because a procedure is new or sufficient experience is lacking, a patient may be subjected to a risk greater than occurs with standard therapies. In the case of the latter, the risks to the patient are that through ignorance, intent, or negligence a procedure will be unnecessarily applied; that it will be applied in a negligent manner; that it will be ineffective; or that it will cause anomalous injuries or results. Generally, however, a therapy is standard or accepted because its risks are known and there is some basis for thinking that on balance its application will benefit the patient. A boundary activity, on the other hand, subjects a patient to these risks and more. For while with an accepted therapy the patient has some reasonable expectation of benefit, with innovative therapy the risk is greater that the therapy will not work or that it will have harmful effects of its own, if only because its effects are unknown. These risks are greatest with the first use of an innovative

therapy, but continue to be substantial until sufficient data on its effects exists. There is also a greater risk that the therapy will be applied negligently or without adequate skill, because due to its newness, physicians have not become skillful in applying it.^{29/} There is also a greater chance of anomalous results occurring if only because it will not yet be known which patients are subject to anomalies. These risks include both the loss of an alternative, accepted therapy (though inadequate), and injuries directly caused by application of the new therapy.

While some added risk appears likely because of less experience with an innovative therapy, it is a question for empirical research how significant this additional risk is. Many accepted therapies have never been validated as effective, and to some extent, may impose risks similar to those of innovative therapy. On the whole, however, it seems reasonable to differentiate accepted and innovative or boundary activities by the knowledge that is known about their likely risks and benefits. Serious deficiencies in our knowledge of the effectiveness of standard therapies does not change the fact that in using a therapy that is relatively unknown, the risks of injury or ineffectiveness is apt to be greater.

A second type of risk in boundary activities is that the physician's decision to undertake the procedure and his disclosure to the patient may be influenced by scientific, career and future patient factors rather than by the interests of the patient alone. These factors will lead him to undertake a procedure that imposes an undue risk (unfavorable risk-benefit ratio) on the patient, and perhaps to influence or manipulate the patient's consent. With accepted therapies, as debates over prepaid delivery systems and

utilization review show, factors such as profit, efficiency, or specialty orientation may also conflict with the patient's interest. While such decisions are deemed unethical and are decried by the medical profession, they may be inherent in the practice of any profession, and hence are left to professional discipline or tort remedies.

With a boundary activity, which involves a departure from standard practice out of a sense that a better procedure exists, there exists, in addition to the conflicts inherent in any professional practice, the possibility that the physician's activities will be motivated or influenced in part by scientific or career aspirations, or by the desire to develop a technique that will benefit future patients. That is, the physician's decision, and his communication with the patient concerning it, will be influenced to some extent by personal or career considerations that go beyond the immediate interests of the patient, thus leading to a decision to employ an innovative therapy that would not have occurred if the patient's interests alone were considered. The recognition that the investigator's loyalties to the subject-patient were under great pressure from loyalties to future patients and career goals has led, in the case of experimentation, to the development of review and consent procedures to assure patients' interests do not suffer, presumably because existing control mechanisms were inadequate to protect patients.

With boundary activities, the question thus is whether, and under what circumstances, patient or other interests are likely to predominate. It may be that with many boundary activities the return to the doctor in terms of career and future patient goals is no different than in the application of

an accepted therapy, or that if some nonpatient concerns are present, they are neither so strong nor dominant as they are in formal research. In other instances, such as the case of Florentino v. Wagner,^{30/} where a surgeon's decision to use an innovative spinal operation led to serious injury to several patients, the decision to use the innovative therapy and the information disclosed to the patient may be strongly influenced by the desire to develop a procedure at the expense of the patient. Since boundary or innovative activities may involve both poles of patient concerns, an important question is (1) ascertaining the frequency and (2) identifying the circumstances in which patient interests are likely to be secondary.

In addition to increasing risks to the patient, a third potential problem with boundary activities is that they generally do not occur in a manner likely to maximize the reliability of data deriving from their use. Since a boundary activity involves a therapeutic use of a procedure whose efficacy or risks are still so unclear that it has not yet become accepted therapy, it is important from the perspective of future patients and medical science generally that reliable information be obtained about the activity's benefits, risks and efficacy. Without such data the future patient who receives or does not receive a particular innovative therapy is at greater risk than if the earlier uses of the therapy had occurred under circumstances and in a manner that would have maximized the chance of obtaining reliable data. It is unlikely, however, that most boundary activities maximize the chance of deriving reliable data. By definition, as it were, the physician will not conceive of his activity

as being experimental, and hence will not apply it in a methodologically sound way, for in most cases he thinks he is doing therapy.^{30a/} Even if nonpatient considerations are strong in the decision to use a therapy, at best the result will be a one patient experiment, whose outcome cannot always be meaningfully extended, even if it is disseminated, to other cases. There is also the danger that innovative therapies which are effective when used in an uncontrolled setting will appear successful and become accepted when they are actually harmful or ineffective. Once accepted, it is difficult to conduct the controlled trials to test their efficacy which may be desirable, and even necessary, to protect patient interests. The recent history of medicine contains several examples of innovative therapies being widely adopted for a period as standard because early uses did not occur in the context of methodologically sound clinical trials which could have yielded reliable data regarding use of the therapy with future patients.^{31/}

B. Adequacy of Present Controls

While it seems reasonably clear that use of innovative therapy creates risks to the patient beyond those that exist in the ordinary therapeutic situation, risks which may be similar in kind to those that exist in research, and also creates the risk that maximum possible knowledge will not be forthcoming from each instance of use, it does not follow that new controls must be devised for boundary activities. Rather, the adequacy of existing control mechanisms in minimizing these risks must be examined. Two types of controls that impinge on the use of innovative therapy will be examined to determine whether it is likely that

either or both provide physicians with sufficient incentives to minimize the risks to patients.

1. Tort Liability

The possibility of tort liability impinges on the use of innovative therapy in two respects. First, a patient injured from the use of an innovative therapy can seek money damages in a civil suit claiming negligence or malpractice in the decision to use the innovative therapy.^{32/} Since the physician will by definition have deviated from accepted, standard professional practice, recovery will depend upon whether reasonable, prudent care in the circumstances would encompass use of the innovative therapy. If the risks to the patient from the therapy itself and the foregone alternative are greater than the likely benefits, then the physician will be liable whether or not the patient consented to undergo those risks.^{33/} On the other hand, the physician will not be liable if he can show that it was reasonable to think that the benefits of the innovative procedure outweighed the risks, including the loss of benefits from foregone alternatives.

Second, a physician could be liable for the use of an innovative therapy if he failed to disclose information required for legally effective consent. Depending on the jurisdiction, recovery here will depend on the amount of information disclosed. In the majority of jurisdictions the physician will be required to disclose only that information which physicians in that situation customarily disclose. Since it is unlikely that there will be a practice established concerning disclosure for the specific therapy involved, the question will be what physicians disclose

about innovative therapies in general, or about innovative therapy for this type of disease.^{34/} A strong minority of jurisdictions, however, require that the physician disclose all information material to the decision of a person in the patient's position whether or not to undergo the procedure. Ordinarily the risks and benefits of the proposed procedure, the risks and benefits of alternative procedures, and probably, the innovative or experimental nature of the procedure would have to be disclosed.

The question, thus, is whether the possibility of tort liability for unjustifiable uses of innovative therapy or for failure to disclose relevant facts will induce doctors to use innovative therapy only when it will reasonably provide a net benefit to the patient, and the patient consents. The ability of the tort system to achieve these goals must be questioned. The tort system is not calibrated to deal with every deviation from ethical conduct. First, it operates only after an injury occurs. Use of innovative therapy may be highly unethical as where the risk is much greater than any benefit to the patient, but unless the risk materializes, no tort remedy is available. Second, where the risk does materialize, a number of factors may operate to prevent a successful suit. The patient may be unaware of a wrong, the injury may not be worth the cost of litigation, he may be unwilling to sue, he may lack the resources, etc. Finally, if a suit is filed, the chances for recovery may be slim. Most malpractice cases are decided favorably to the doctor.^{35/} The patient will have to show that he is worse off than he would have been if he had not undergone the innovative therapy, and this may be difficult. For all these reasons, the threat of a law suit and

legal liability may not prevent physicians from using innovative therapy in situations that ignore patient interests, if use otherwise seems justified. Of course, one might argue that the physician will be all the more careful when using innovative therapy precisely because the chances of liability are greater, but empirical data to evaluate this claim is lacking.

Similarly, the law of informed consent will not necessarily assure that the patient will be informed to the same extent that ethical practice requires, or that would occur through some other control process.^{36/} First, the standard for disclosure will be considerably less in those jurisdictions that allow medical custom to define the limits of disclosure,^{37/} and even in Canterbury-type jurisdictions, it is not yet established that the innovative nature of a procedure must be disclosed. Second, whatever the standard for disclosure, implementing the standard legally will depend on the occurrence of injury, willingness and ability to sue, and establishing that if additional information had been disclosed, the patient would not have consented. Though not insurmountable, these are formidable barriers raising doubts about the efficacy of tort liability to assure ethical practice in disclosing relevant information about the use of an innovative procedure.

Two further aspects about tort liability should be noted. The first is that in at least one respect, the tort standard of reasonableness based on a calculus of risks and benefits to the patients may be more favorable to the patient than the HEW standard employed by IRB's because benefits to future patients will probably not count, as the HEW standard allows. Second, the limitations of the tort system arise from the way

the system is presently constituted. Changes in tort liability rules that permit awards of damages on the showing of injury alone, or that otherwise facilitate suit, may well make the liability system an effective device for controlling the possible abuses of innovative therapy.

2. Peer Review

In addition to the incentives provided by the legal system to give primary weight in boundary activities to patient interests (that is, to judge the risk-benefit ratio in terms favorable to the patient), a variety of professional norms and review mechanisms also provide such incentives. In discussing them, the question to be kept in mind is to what extent they are likely to counter tendencies in the innovative therapy situation to disregard patient interests and thus assure an acceptable quality of care in these activities.

a. Professional Ethics and Codes

Professional ethics, as exemplified in codes and medical ethical writings, generally require loyalty to the patient, and do not sanction compromise of patient interests for personal or career goals, or even simply to advance science.^{38/} Since such codes and norms are generally hortatory, carry no specific sanctions, and may often not be clearly applicable to boundary activities, one might justifiably display skepticism as to their efficacy in assuring protection of patients in innovative therapy situations. No doubt many physicians have internalized and comply with these ethical precepts, but at present there is not substantial evidence showing that adherence to a code of medical ethics alone will prevent patient abuses in innovative therapy or improve the methodologies

with which they are used.

b. Informal Peer Review Mechanisms

Another mechanism that might provide incentives to apply innovative therapy in ways protective of patients are various informal and formal professional review mechanisms. Medical audits, utilization review, tissue committees, credential committees, academic rounds, and the like, all review physician decisions to some extent and presumably have various sanctions to induce compliance. To the extent that colleagues and review committees reviewed boundary activities and evaluated their ethical justification, a physician might be induced to make decisions with appropriate risk-benefit ratios and consent procedures, for fear of peer disapproval, censure, nonreferrals, or perhaps more stringent sanctions such as limitation or termination of hospital staff privileges.

Without data available on the precise scope and details of these review mechanisms, it is difficult to evaluate their efficacy in minimizing the abuses of innovative therapy. However, a number of factors cast doubt on their efficacy. First, there is no guarantee that most boundary activities will come to the attention of peer review mechanisms. The frequency of review will vary with the setting and type of activity, and no doubt may occur more often with surgical procedures ^{39/} or practice in an academic setting.^{40/} Secondly, even if particular boundary activities are reviewed, one cannot be sure that the criteria and standards applied will coincide with the socially desired criteria. Professional standards as to when risks and benefits of an innovative therapy are appropriate might unduly weigh scientific and future patient interests

over those of the patient.' Also, medical audit and review programs do not generally look at the consent process.^{41/} Finally, peer review mechanisms do not always carry the sanctions that would induce more desirable behavior, though the potential for so doing could be there. One situation in which peer review mechanisms may be effective is that of the internally or externally imposed clinical moratorium on further uses of an innovative procedure, when great risks to patients become apparent.^{42/} While the moratorium phenomena has operated effectively with innovative cardiac surgery, it appears subject to the same deficiencies as other peer review mechanisms.^{43/} In sum, various peer review mechanisms, if they exist at all, do not appear geared to review innovative therapy in a manner necessarily coincident with what is most socially desired. For this reason, they do not appear to provide sufficient incentives to assure protection of patient interests in innovative therapy situations.

c. PSRO

A brief word about the relevance of PSRO is in order, since once they are functioning, PSRO's will be the most comprehensive peer review mechanism in operation.^{44/} Because of their nationwide scope and review of both institutional and outpatient care, they are likely to pick up more instances of innovative therapy than any other review mechanism. PSRO's also have the power of the purse to enforce their standards, since they may deny payment for inappropriate or unnecessary services. However, because PSRO review is limited to medicare and medicaid patients, most doctor-patient encounters will not be within their ambit. A key question

concerns whether PSRO standards will exclude payment for boundary activities that appear unjustified from the patient's perspective. Since norms will be set by physicians, this will depend on whether norms reflect patient or professional interests. Secondly, whatever the norms, their efficacy will depend on their implementation — on the willingness of PSRO's to take a firm stand against dubious professional practices. One can expect the more outrageous conduct to be penalized, but many cases of innovative therapy may not fall into that category.^{45/} Moreover, it is not clear that PSRO's will identify and prevent abuses of innovative therapy that slip by the tort system and other review mechanisms. In sum, while some peer review procedures, particularly PSRO's, may help define standards of acceptable practice, their efficacy in preventing or deterring unacceptable instances of innovative therapy is unclear. Data is lacking on the extent to which they provide incentives beyond that of the tort system to honor patient interests in applying new therapies.

III. Alternatives for Control

If one concludes that the risk to patients from boundary activities is significantly greater than with accepted practice and that tort and peer review mechanisms provide insufficient incentives to protect patient interests, then several alternatives for minimizing patient injuries from innovative therapy may be considered. Each alternative, however, has costs, ranging from the costs of administering a review system to the costs borne by patients when an innovation beneficial to them is not available. With each alternative the inquiry is the same: do the benefits in patient protection, personal autonomy, and increased knowledge outweigh the costs.

Before analyzing specific suggestions for improving tort and peer review mechanisms, it is necessary to consider whether boundary activities should be thought of as experimentation. Whether a special set of rules or controls are to be applied to innovative therapy depends first of all on whether a special set of rules is to apply to clear cases of experimentation. Aside from activities specifically funded by HEW, there are at present no legal controls on experimentation or innovative therapy other than general principles of tort law, which appear to treat experimentation and therapy identically. Unless legal controls on experimentation are developed, it would seem a fortiori that no controls should be forthcoming for innovative therapy, since the risks they pose seem much less than those of experimentation. However, assuming that controls for experimentation are developed, either legislatively or administratively, a question remains whether (1) they should also apply to innovative

therapy; (2) a special set of rules for innovative therapy should be developed; or 3) innovative therapy should be treated like accepted practice. If the same rules are to apply to experimentation and innovative therapy, no problem of definition arises, for experimentation can be broadly defined to include at least all intentional deviations from customary practice.^{46/} If situation (2) or (3) applies — innovative therapy is to be treated differently from experimentation, either with or without a special set of rules — then criteria for distinguishing innovative therapy from experimentation must be developed.^{47/}

A. Should Innovative Therapy Be Treated as Experimentation

Assuming that through legislative or administrative action experimentation will become a distinct legal category with specific liability, disclosure or review requirements, the question is whether experimentation should be defined to include all intentional deviations from standard practice, including innovative therapy, as many current definitions and experts suggest.^{48/} Since an innovative therapy is usually insufficiently proven or tested to be established as effective, calling it experimental seems appropriate. Moreover, the incentives that exist in the clearly experimental situation to disregard the patient's good in order to advance the interests of the researcher or third parties, may also exist in a boundary activity, though they are not as likely to be present or, if present, to be as strong. Defining or treating innovative therapy as experimentation, with prior review by an IRB,^{49/} will thus lead to risk-benefit calculations more favorable to

patients, will lead to more fully informed patients, and possibly will improve the reliability of data generated by innovative therapy by "experimentalizing" its use.^{50/}

Requiring prior review by an IRB for all uses of innovative therapy, as well as for experimentation, however, may pose significant problems. Assuming the requirement is legislatively imposed, then IRB's will have to be constituted in numerous institutions and settings where they do not now exist. For while research may occur in limited settings, innovative therapy is likely to occur wherever medicine is practised. In addition, it is not clear that all uses of innovative therapy in an office practice can be brought under an IRB umbrella. Such a requirement would constitute a governmental intrusion into medical practice far greater than has yet existed. It is highly likely that the medical profession would resist an enactment of such legislation or would challenge it in court if passed.^{51/} Indeed, it is not at all clear that the dangers of innovative therapy are so great that the incremental benefit from IRB review would constitute the compelling state interest justification necessary if such legislation is to be constitutional under Doe v. Bolton.^{52/}

If IRB review is required only for innovative therapy in institutions receiving HEW funds, problems still exist. First, if the requirement is the receipt of any HEW funds, then most hospitals and many physicians would qualify, if they receive Hill-Burton, Medicare, or Medicaid funds. Secondly, existing IRB's would be hard-pressed to review every instance of innovative therapy given their present resources and workload. A permanently constituted review process, with staff, etc.,

would be essential. This expense would probably be passed on to consumers, thus increasing the cost of health care. Third, some degree of intrusion into the doctor-patient relationship will occur, with additional constitutional difficulties as to Congress's power to condition federal grants on regulation of nonfunded activities.^{53/} IRB review could be limited to innovative therapy directly funded by the government, but then only a small percentage of boundary activities would be regulated.^{53A/}

In addition to problems of constitutionality, scope, administrative cost and implementation, two further factors cast doubt on the wisdom of requiring IRB approval of all innovative therapy, as many institutions now purport to do in the general assurances given DHEW.^{53B/} One is that despite similarities to experimentation, innovative therapy may be primarily therapeutic and for the benefit of the patient and, only secondarily may involve the concern for science and future patients that creates the researcher's conflict of interest in experimentation. Such incentives may occasionally operate, but on the whole, they appear to be considerably diminished in strength and alone may not justify the tremendous costs and burdens of a prior review system, particularly when existing liability and disclosure rules will prevent the most egregious abuses. Secondly, these doubts are all the more compelling when we consider IRB review will not necessarily assure more complete disclosure or better risk-benefit ratios for patients. No data establishing IRB efficacy in either regard now exists. In fact, available data suggests

that they may have little effect, particularly on improving the consent process.^{54/} Moreover, IRB balancing of total benefit against patient risk could put the patient's interests secondary to scientific advancement, though this may be only a theoretical concern. While IRB's in some places may be effective monitoring and protective devices, or may become so with certain changes, given existing data and the institutional context in which IRB's operate, one should hesitate multiplying them and expanding their scope at great cost unless there is a reasonable chance that they will achieve the goals desired.

This position differs with Robert Levine's statement that "in general innovative therapy should be conducted and reviewed as if it were research."^{55/} He further states:

For practical purposes, the definition of research as provided in this paper, includes innovative therapy (or innovative practice). This means that any innovative practice in which the deviation from customary practice is substantive should be conducted so that it most closely approximates the standards of good research (as defined by the relevant scientific discipline) without obstructing the intent to bring direct health benefit to the patient-subject. It further means that the proposed innovative activity should be reviewed by an IRB, that the consent negotiation indicate that the activity is being performed with — at least in part — research intent, and so on. ^{56/}

While recognizing that emergency^{57/} and nonsubstantive deviations^{58/} from customary practice might not warrant treatment as research, Levine's

position rests on a particular definition of research and on the need to maximize knowledge from a particular use of an innovative therapy. This position seem erroneous in three respects.

First, defining research as including all nonsubstantive deviations from customary practice seems overinclusive. As discussed more fully below, neither deviation from customary practice nor intent to obtain new knowledge adequately distinguishes research from primarily therapeutic activities. Rather, the distinguishing feature should be a primary intent to obtain new knowledge beyond the needs of the patient. When applied to innovative therapy, this criterion will distinguish emergency and "nonsubstantive" uses of innovative therapy, as well as substantive uses of innovative therapy which are primarily therapeutic in intent and only secondarily involve obtaining knowledge beyond the patient's needs. Use of untested therapies is certainly of concern, and may require special safeguards. But when their use is not influenced by interests contrary to the patient's needs there is no need to treat innovative therapy as research.

Second, Levine may place undue emphasis on the need for studying all innovative practices systematically during the process of innovation.^{59/} The goal is certainly a worthy one and should be encouraged. However, one should not be overly optimistic that IRB review will lead to better controlled uses of innovative therapy, without more evidence that they are capable of turning single uses of innovative therapy into controlled clinical trials.^{60/} Also, this concern places the interests that future patients have in safe,

efficacious therapies above the immediate interest of the patient and doctor in applying an innovative therapy. There may well be situations in which use of an innovative therapy is delayed or even denied, to the detriment of a patient, because the physician cannot readily experimentalize its use, in order to maximize knowledge from its application. Although better testing of innovative procedures is desirable, achieving that goal should be separated from the different goal of protecting patients from the conflicting interests of research situations.

Third, Levine overlooks the legal and administrative problems that would arise if all nonsubstantive innovative therapy had to obtain prior approval of an IRB. If review is required for activities other than those directly funded by DHEW, political, legal and constitutional problems arise, not to mention the cost and administrative difficulties in setting up new IRB's or overloading existing IRB's with substantially more business. Administrative difficulties alone should not prevent protection of human subjects. But these costs should not be incurred unless there is a reasonable certainty that they will actually produce greater benefits for patients.

B. Should Innovative Therapy Be Treated Differently From Accepted Therapy

If there are good reasons for hesitancy in treating all innovative therapy identically with experimentation, particularly in the respect of prior IRB review, the question remains whether there should be any special controls for boundary activities (though short of

the controls for research), or whether innovative therapy should be handled like accepted therapies. In either case, however, it will be necessary to define a boundary between research and innovative therapy, no matter how innovative therapy may be regulated. This section first discusses distinguishing innovative therapy from experimentation by the physician's intent, and then discusses the costs and benefits of various alternatives for dealing with innovative therapy.

1. Distinguishing Innovative Therapy From Experimentation

The criteria proposed to distinguish those activities that are to be regarded as research and subjected to a special set of controls, generally include three elements: (1) untested or unproven efficacy; (2) a deviation from standard or customary practice; and/or (3) an intent or aim to develop new knowledge. For example, the DHEW regulations, through a definition of "subject at risk" stress deviation from standard practice:^{61/}

activity which departs from the application of those established and accepted methods necessary to meet his needs.

Robert Levine defines research both in terms of intent and deviation:^{62/}

any manipulation, observation, or other study of a human being — or of anything related to that human being that might subsequently result in manipulation of that human being — done with the intent of developing new knowledge and which differs in any way from customary medical (or other professional) practice.

Martin Norton focuses on lack of proof of efficacy and intent:^{63/}

Experiments can be described as: Those procedures that are untested or unproved with respect to clinical efficacy or are by their very nature not related to the therapy of the patient but rather performed solely for the purpose of obtaining scientific data.

These definitions, which are typical of current attempts to define research,^{64/} suffer from under or overinclusiveness. A definition is overinclusive if it is so broad that it encompasses clearly accepted medical procedures, as would occur if experimentation meant every use of an unvalidated or unproven procedure, as Norton and others suggest. Unvalidated practices may well pose risks for patients and deserve close scrutiny, but the fact that an accepted medical procedure used with therapeutic intent has not been reliably validated does not mean that it is experimental. While such a definition of experimental serves to call attention to the need for more thorough testing of ordinary therapies, it clashes with common usage and risks confusing the problems of insufficient testing with the quite different problems that arise when persons are used in biomedical experimentation.

A second criterion of the experimental — deviation from customary practice — also appears overinclusive. One may deviate from standard practice for many reasons — out of ignorance, negligence, disagreement with the standard, or in an attempt to find a better therapy. Since we do not regard every deviation from standard practice as an experiment, this criterion will not do. Indeed, if it were sufficient, it would also be underinclusive, for it would exclude experiments with an accepted

therapy, though clearly one could conduct an experiment to compare the efficacy of two accepted therapies.^{65/} Of course, most instances of research or experimentation are deviations from accepted therapy. However, this seems due to the aim, intent or purpose with which they are done and not simply because they are a deviation from a customary practice.

A third criterion focuses on the state of mind of the physician and asks whether there is an intent, aim, or purpose to develop data or knowledge. Even this criterion risks overinclusion unless qualified, for most tests and procedures in accepted therapy are done with the intent or aim of obtaining knowledge, such as knowledge about the patient, his body functions, the effect of a therapy, and the like. Furthermore, this knowledge is usually new, in that it was not previously known about the patient. Thus the intent necessary to define research cannot be the intent to obtain new knowledge, for that intent clearly characterizes therapeutic activities, as Moore, Norton, and others have recognized.^{66/} Rather, the intent must be to test or gather knowledge about a condition, test, outcome, or procedure beyond the needs of the patient, even though the patient may also benefit from the effort. The utility of this definition is that it focuses attention on interests and aims other than the immediate interests of the patient, which is why there is concern with experimentation. Thus a deviation from standard therapy which benefits a patient would be research if it would not be done if no intent to gather data beyond the needs of the patient existed, and would not be research if it would have been done absent an intent or purpose to gather data about the procedure beyond the immediate needs of the patient. A deviation from standard practice done

solely with the intent of benefitting the patient may amount to negligence or quackery if there is no reasonable chance of helping the patient.

This definition should serve to distinguish those activities for which special protections are needed because nonpatient interests are paramount. Though the intent criterion applies both to conformity to and deviations from accepted therapy, it also distinguishes those instances of deviation from customary practice which should be treated as experimentation because of the presence of interests that conflict with those of the patient. Intentional deviations from standard therapy are thus considered research if done primarily with intent to develop new knowledge about the procedure or test, beyond the needs of the patient, and therapy, if done primarily with an intent to benefit the patient, and knowledge about the procedure itself is secondary.

Two problems with the intent criterion should be mentioned. One concerns a distinction between general and specific intent. In law one is often held to intend the natural and probable consequences of one's act, even though one specifically intended or aimed only to do the act producing those consequences.^{67/} Since a particular therapeutic use of an innovative therapy may naturally yield knowledge concerning use with other patients, one might argue that a general intent to use the therapy should be treated as an intent to derive knowledge for other uses, merely because such knowledge is a likely or natural and probable consequence of its use. Usually a physician will know that such knowledge will result, so that the possibility of a nonpatient benefit might, albeit subconsciously, influence his decision to use the therapy, even though at the time of use he specifically

intends only therapy and benefit to the patient. However, if an interest conflicting with the patient's operates only on the subconscious level, it does not differ from the physician's interests in extra income, time, etc. that may conflict with patient interests in situations of ordinary therapy and which arguably deserve no special protection. The strongest case for treating the general intent to use an innovative therapy as equivalent to a specific intent to acquire knowledge beyond the patient's interests would exist in the first use of a drug or new surgical procedure. Here the development of knowledge is inevitable,

, and here it is likely that the intent to gain new knowledge is strong, or at least equivalent to the therapeutic intent.^{68/} Thus a standard of specific intent to produce new knowledge for use by others will identify most of the situations of innovative therapy that are of concern. Even if a special rule were justified for first uses of a new procedure, this would not change the fact that later uses may be specifically intended only to benefit the patient.

A second problem with an intent criterion is its implementation. If the presence of such intent transforms a therapeutic situation into research, and thus touches off a need for prior review or other procedures, then a review system will be overdependent on the good faith of physicians, when their loyalty to patients is itself the issue. For a boundary situation to be subject to special controls, the physician will have to determine what his primary or specific intent is. If he determines that his intent is research, then he must submit the procedure to review or whatever other mechanisms exist. Such a system, it may be argued, lends itself to abuse,

because physicians will have (1) an incentive in searching for their purpose to emphasize its therapeutic aspects, when research plays a dominant role; and (2) no sanctions can be applied for their failure to submit to a review process, even if the requisite intent is present, because it could never be established that they possessed a research rather than a therapeutic intent.

No doubt some physicians, as a result of this system, might be quick to downplay or deny nontherapeutic intent in boundary situations. At a certain level, however, every regulatory system is dependent on the good faith of the regulated. Defining all innovative therapy as experimentation would not, unless every physician decision were monitored, yield better results, because it would still be dependent on a physician recognizing or admitting that a procedure is, in fact, a deviation from standard practice and, then, deciding to submit it to review. As with the intent standard, the physician will have incentives to find that his procedure is actually recognized or accepted by some segment of the profession, or if that is impossible, of simply not submitting it to review.^{69/} Absent a monitoring system, there will not be any behavioral indication that the procedure is innovative rather than accepted, as there might be with clear-cut experimentation.^{70/} While the intent standard may pose compliance problems, those problems are not likely to be greater than would exist with a deviation from customary practice standard, which, as we have seen may be underinclusive anyway. It does have the advantage of drawing a fairly clear line, which each physician can personally feel (and if in doubt, can call research). Since any control system will have to rely

on physician compliance to an important extent, that fact alone should not render the intent standard unworkable.^{71/}

2. Controls for Innovative Therapy

If one agrees that all innovative therapy need not be treated like research, and that a boundary based on specific intent is a workable device to identify those instances of innovative therapy which involve research, the question remains whether therapeutic deviations from standard practice primarily to benefit the patient need any safeguards or controls in addition to those that apply to accepted therapy.

a. Argument for No Additional Controls

The argument for no additional controls would be that where the physician intends to use an innovative therapy primarily to benefit the patient, no special protection is needed because no nonpatient interests beyond those that ordinarily exist in therapy are operative. Rather, the risk is that through ignorance, misinformation, or negligence a physician will miscalculate the risk-benefit ratio and impose unreasonable risk on patients. However, this danger/^{to some extent}exists in any therapeutic situation, and the physician will have the usual incentives to work for the benefit of the patient. Moreover, he is likely to be especially wary of a lawsuit where a risk of injury is greater because of uncertain knowledge and hence will be more careful about obtaining consent and assuring that the patient stands to benefit. Particularly in jurisdictions requiring disclosure of the innovative nature of a procedure, the legal system already provides enough protection. Further controls would be an unnecessary and unwarranted

intrusion into medical practice.

The validity of this argument rests on whether one thinks that sufficient incentives to respect patient interests and autonomy already exist, or whether because of lack of knowledge or deficiencies in the legal system, physicians are apt to miscalculate risks and benefits to the detriment of the patient.

b. Additional Controls

If one thinks that on balance physicians may, even when acting primarily for the patient's benefit, tend to miscalculate risks and benefits to the patient's detriment more often than would occur with accepted therapy, several alternatives to improve their calculation exist

(1) New Liability and Disclosure Rules

One alternative would be to change current liability and disclosure rules, to assure that the physician accurately judges that potential benefits outweigh the risks, and that full disclosure occurs. Again, since it is unlikely that special liability and disclosure rules for innovative therapy would be enacted independently of such rules for experimentation the question is whether enacting special liability and disclosure rules for experimentation is warranted. With regard to liability, physicians engaging in experimentation could be strictly liable for any injury resulting from use of the experimental procedure, whether or not negligence occurred. The effect of this rule would be to internalize to the research project itself the costs of injuries now borne by the subjects.^{72/} If effective, it would force the researcher

(or institution) to calculate the chances of such injury and to determine whether this additional cost is outweighed by the benefits to be achieved by the research. Strict liability would thus be justified on the ground that the physician is in the best position to decide whether the likely benefits will outweigh the costs.

Such a rule would be socially desirable if, in fact, physicians made fairly accurate predictions as to all the costs and benefits of an experiment, including benefits to future patients and the costs to subjects, and if they were in a position to capture enough of the benefits to cover the costs they will incur if liable. If they are bad predictors, or if the benefits they capture do not outweigh their costs, even if all benefits outweigh their costs, then socially desirable research will not take place and future patients will unnecessarily suffer.

A more precise analysis of a strict liability scheme for experimentation injuries, which is needed before such a rule can be recommended, is beyond the scope of this paper. The key question concerns whether such an approach will adequately compensate injured patients while not reducing research below a socially optimal level. Assuming such a rule existed for experimentation, the question is whether it should be extended to innovative therapy that is primarily therapeutic in intent.⁷⁴ Again, the answer to this question will depend on whether such a rule will deter uses of innovative therapy that, on balancing risks and benefits, seem justified. Unless a nonfault or strict liability rule applies to all medical injuries, physicians may well avoid deviations from standard therapy aimed at benefitting the patient, because of fear of liability,

even though on balance the patient will be better off.

A similar inquiry would occur if the new liability rule were less drastic, as would be a rule which shifted the burden of proof in cases of intentional deviation from standard therapy to the defendant physician, requiring him to prove that the likely benefits to the patient outweighed the risks. Such a rule might well induce doctors to be more careful in their use of innovative therapy, without preventing those applications of a new therapy in which the benefits outweigh the risks to the patient.

Enactment of special disclosure rules for both experimentation and nonresearch innovative therapy poses fewer problems than do liability rules. In Canterbury-type jurisdictions, disclosure of all information material to a patient's decision to submit to experimental or innovative therapies is now the disclosure rule. Requiring a similar rule in all jurisdictions for both experimental and innovative procedures, if it is not already required because of a professional custom in having more complete disclosure for research,^{75/} should pose no major problems. It might increase the time a physician spends in obtaining consent, but the benefits thereby obtained seem greater. While more complete disclosure of risks might lead some patients to reject an innovative procedure which others would have chosen, this should not be of major concern, for the lost benefit will be a result of the patient's informed choice.

At the very least, then, a disclosure rule should be enacted which requires that patients be informed of risks, benefits, and discomforts of experimental, innovative and alternative procedures, and the new or

experimental nature of a proposed therapy. Enactment of a strict liability rule for injuries resulting from experimental or innovative therapeutic procedures requires a more precise analysis beyond the scope of this paper and should be explored. Shifting the burden of proving the reasonableness of a procedure, however, poses fewer problems and could fruitfully be enacted now.

(2) Improving Peer Review

A second alternative, if one finds existing controls inadequate for innovative therapy primarily therapeutic in intent, would be to develop peer mechanisms that through review and feedback to the physician, induced physicians applying innovative therapy to make better risk-benefit calculations and more complete disclosure to patients. Alternatives here range from education and development of precise norms and criteria for use of innovative therapies, to monitoring of physician activities on a continuous or random basis. The former may be a useful addition, but one should not be overconfident of its impact. The latter might be very effective, but involves tremendous costs and difficulties in arranging. If created solely for uses of innovative therapy, the costs may be hard to justify. Yet developing effective quality control mechanisms for all medical decisions is far from realization. Consideration should at least be given to developing and enforcing a practice of preuse consultation, and after-the-fact review of applications of innovative therapies, though the precise details of such a system await further study.

IV. CONCLUSION

Public Policy for innovative therapy depends on the extent to which innovative therapy poses risks for patients beyond those that exist in ordinary therapy, and, secondly, on the efficacy of existing legal and peer review mechanisms in minimizing those risks. If one concludes that a special set of controls is needed, a major policy issue is whether all innovative therapy is to be regarded as research and subject to the controls applicable to research, or whether there are some instances of innovative therapy to which the controls of research need not apply. Since a physician may use innovative therapy primarily for the patient's benefit, with no intent to acquire knowledge beyond the needs of the patient, the career, scientific, and future patient interests that call for special protections in research may often be absent. In those situations, distinguished by the specific intent of the physician, treatment of innovative therapy as research is unnecessary to protect patients from the conflicts of interest inherent in research. Requiring IRB approval for all innovative therapy would also raise serious administrative, political, and legal problems at a time when it is unclear that IRB review will substantially enhance patient interests and lead to more informed consent, where no research intent is present.

Where there is a specific intent to acquire information about the procedure beyond the needs of the patient, it is appropriate to regard the physician as engaging in research. The intent to obtain knowledge may influence the physician's disclosures to the patient, and his decision to use the therapy. Innovative therapy in this situation should be subject

to the same controls as research, including prior IRB review and the same liability or disclosure rules. The key policy issue here is whether these controls will apply to all research, to research occurring in institutions receiving federal funds, or only to research directly supported by federal funds. Each alternative raises unique problems of scope, political feasibility and constitutionality which recommendations for controlling research should not ignore.

Having divided the universe of innovative therapy into two classes on the basis of physician intent, the question remains whether primarily therapeutic innovative therapy should be subject to special controls or whether it should be treated like ordinary therapy. Assuming the former, these controls should not be more stringent than the controls enacted for research, because the risks are smaller. While further study of a strict liability rule for injuries occurring in primarily therapeutic innovative therapy is needed, shifting the burden of proof to the defendant physician may be more feasible. Requiring as complete disclosure as occurs for research in a Canterbury-type jurisdiction is clearly in order. In addition, the medical profession should be encouraged to develop clearer standards for using innovative therapy and review mechanisms that will informally monitor physician use of them.

FOOTNOTES

1. Congress, in establishing the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, explicitly recognized the problems presented by boundary activities. It specifically directed the Commission to consider "the boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine", - in carrying out its study of ethical principles, guidelines and recommendations to the Secretary of HEW. P.L. 93-348, Sec. 212(B)(i).
2. 45 C.F.R. Sec. 46.3(b). One could argue, however, that a departure from standard therapy does not place a subject at risk if there is a reasonable basis for thinking that only such a departure could benefit the patient. In that case such a departure would be one of "the established and accepted methods necessary to meet his needs," if in fact it is standard medical practice to depart from accepted therapies when there is no reasonable hope of success and the benefits of the non-standard procedure outweigh the risks.
3. There is currently ambiguity, if not actual confusion, as to whether DHEW has the authority to require that institutions receiving DHEW funds submit all research with human subjects, whatever the funding source, to the review procedure required for research directly funded by HEW. As a matter of practice, HEW presently appears to take the position that an institution's general assurances pursuant to 45 C.F.R. Secs. 46.1 - .22 must include an assurance that all behavioral and biomedical research, however funded, will be reviewed by an IRB and consent protected.

However, the authority for this position is less than clear. Section 212 of P.L. 93-348, directed the Secretary of HEW by regulation within 240 days to require entities applying for grants under the Public Health Service involving research with human subjects to give assurances that all research involving human subjects at the institution would be reviewed. The regulations issued pursuant thereto, 40 Fed. Reg. 11854-58 did not include such a regulation. Although one could argue that 45 C.F.R. Sec. 46.21(b)(2) accomplishes the mandated purpose, it is sufficiently ambiguous, and so clearly preceded P.L. 93-348, that it hardly seems to discharge the duty required of the Secretary.

Assuming the existence of the regulation required by P.L. 93-348, its constitutional validity remains an open question. While Congress may attach conditions to its grants under the spending power, the Tenth Amendment would require that there be some limits on the conditions it may attach. Based on language in United States v. Butler, 297 U.S. 1 (1936) one may argue that grant conditions must be reasonably related to the purpose of the grant, and cannot regulate

activities which are not funded under the grant. If the courts so limit Congress' conditional spending power, P.L. 93-348 and similar attempts to regulate non-government funded research with human subjects would be unconstitutional. For a more detailed discussion, see "Comment, The Federal Conditional Spending Power: A Search for Limits," 70 Northwestern L. Rev. 293-331 (1975).

4. Under Roe v. Wade, 410 U.S. 113 (1973) and Doe v. Bolton, 410 U.S. 179 (1973), such intrusion would be unconstitutional unless a compelling state interest that outweighs the physician and patient's right to privacy in their relationship, can be established. It is far from clear that the possibility of abuse in using innovative therapy is so frequent that its avoidance would constitute a sufficiently compelling state interest.
5. A more technical formulation of the general rule is: "a physician has the obligation to his patient to possess and employ such reasonable skill and care as are commonly had and exercised by reputable, average physicians in the same general system or school of practice in the same or similar localities." Waltz and Inbau, Medical Jurisprudence 112 (1971); See also Louisell and Williams, Medical Malpractice 8.03-8.07 (1973).
6. See, e.g. Helling v. Carey, 519 P.2d 981 (Wash. 1974).
7. Carpenter v. Blake, 60 Barb. 488 (S.Ct. N.Y. 1871); Smith v. Beard, 56 Wyo. 375, 11 P.2d 260 (1941); Hodgson v. Bigelow, 335 Pa. 497, 7 A.2d 338 (1939); Sawdey v. Spokane Falls and N. Ry., 30 Wash. 349, 70 P. 972 (1902); Jackson v. Burnham, 20 Colo. 532, 39 P. 577 (1895); Kershaw v. Tillbury, 214 Cal. 679, 8 P.2d 109 (1932); Graham v. Dr. Pratt Inst., 163 Ill. App. 91 (1911); Medical Exam of Indiana v. Kaadt, 221 Ind. 625, 76 N.E.2d 669 (1948). See generally, Krisanovich, "Medical Malpractice Liability and Organ Transplants," 53 U. San. Fran. L. Rev. 223, 272-277 (1971), and Waltz and Inbau, Medical Jurisprudence, pp. 179-202, on which this and the following paragraph are largely based.
8. Waltz and Inbau, 190; Karp v. Cooley, 493 F.2d 408, 423-424 (1974). Although some cases have referred to experimentation as a separate ground of liability, the evidentiary requirement for establishing liability remains whether a reasonable and prudent physician would have experimented in those circumstances.

Karp v. Cooley, 493 F.2d 423. While this clearly applies to experimentation occurring in a therapeutic situation, its applicability to non-therapeutic situations is less clear. In those cases liability is likely to depend on the adequacy of consent. For the only reported instance of damages awarded a volunteer for injury resulting from tests conducted solely for purposes of medical research, see Halushka v. University of Saskatchewan, [1966] 53 D.L.R.2d 436 (1965) (Canada) (ineffective consent to anesthetic tests; injuries included "diminution of mental ability"; verdict for \$22,500). In any event, this paper deals only with experimentation occurring in therapeutic situations.

9. Id., Waltz and Inbau, 190.
10. See note 3, supra.
11. 45 C.F.R. Sec. 46.2(b)(1).
- 11a. However IRB review might be said to alter the likelihood of the risks occurring, given an unfavorable risk-benefit ratio. This issue is treated in the discussion of causation that occurs later in this paragraph.
12. According to the discussion in note 3, supra, this is not now the case, even for research directly funded by HEW. In any event, review is not now required by statute for all activity characterized as research, whatever the funding source.
13. Prosser, Law of Torts, 200-201 (4th ed. 1971).
14. Id.
15. Even if violation of the statute is found to be causally related to the plaintiff's injury, a plaintiff who provided a legally valid consent, depending on the information disclosed, could be found to have assumed the risk that injury would occur. For a discussion of assumptions of the risk, see Prosser, 434-457. However, Waltz and Inbau seem to view the matter differently. Op. cit., 199.
16. A similar analysis would apply if IRB review for research, though not statutorily required, was customary practice for (1) HEW funded research, (2) research in HEW funded institutions, or (3) all research whatever the funding source. Failure to conform to a custom of reviews would not in itself produce liability, though a court could hold that it was unreasonable. Questions of causation and defenses of such as assumption of risk and the problems they raise would still exist.
17. See generally, Waltz and Inbau, 152-177, and sources cited therein; Louisell and Williams, Sec. 22.01.
18. Wilson v. Scott, 412 S.W.2d 299 (1967).
19. 464 F.2d 772 (D.C. Ca. 1972).
20. See, e.g., Cobbs v. Grant, 502 P.2d, (Cal. 1972); Cooper v. Roberts, 286 A.2d 676. (Pa. 1971); Wilkinson v. Vesey, 295 A.2d 676 (R.I. 1972); Trogun v. Fruchtman, 207 N.W.2d 297 (Wis. 1973).
21. 464 F.2d 787-788.
22. Fortner v. Koch, 201 N.W.702 (S.Ct. Mich. 1935); Fiorentino v. Wagner, 227 N.E.2d 296 (N.Y. 1967).
23. Presumably the two jurisdictions which adopted the rule, see note 22, supra, would continue to require such disclosure, even though these statements occurred before adoption of a Canterbury-type disclosure standard.

Footnotes

24. 45 C.F.R. 46.3(c) (1-6).
25. 45 C.F.R. 46.2(b) (3).
26. 45 C.F.R. 46.3(c) (1-6).
27. Depending on the precise disclosure rule in effect in a non-custom jurisdiction, HEW rules could require more disclosure than would occur even under a reasonable person standard.
28. See pp. 28-45, infra.
29. This is especially true with surgery.
30. 227 N.E.2d 246 (N.Y. 1967).
- 30a. He also may intend to experiment with this procedure, but intend only a one-patient experiment, rather than undertake to develop a formal clinical trial.
31. A widely noted example was the development of portacaval anastomosis for bleeding esophageal varices which when finally tested was found to lack the supposed efficacy. Warren, "Controlled Clinical Research: Opportunities and Problems for the Surgeon," 127 Amer. J. Surgery 3-8 (1974); Spodnick, "Numerators without Denominators: There is no FDA for Surgeons," 232 JAMA 35-36 (1975); Strauss, "Ethics of Experimental Therapeutics," 288 N.E.J.M. 1183-1184 (1973).
32. Since there is a greater risk of unskillful application with a new procedure, a finding that unskillful application due to newness is negligent would also be a disincentive to use. Aside from this possibility, the possibility of damages because the innovative procedure may also be negligently applied would not appear to create additional disincentives to use.
33. Waltz and Inbau suggest that the plaintiff's assumption of the risk, as manifested in a legally effective consent, would not bar recovery if use of an innovative procedure is unreasonable in the circumstances. See Waltz and Inbau, 199.
34. The disclosure custom will also depend on the effect given the HEW regulations as evidence of a disclosure practice. See pp. 12-13; supra.
35. Report of the Secretary's Commission on Medical Malpractice, 5-20 (1973).

Footnotes

36. Of course, physicians may disclose more information than the law requires.
37. This statement assumes that the HEW regulations will not be taken as evidence of disclosure practice.
38. See e.g., Nuremberg Code of Ethics in Medical Research (1949); Declaration of Helsinki (1964) in Waltz and Inbau 379-383.
39. Presumably scrutiny of surgery by tissue committees and departmental review occurs more frequently than does review of medicine.
40. In patient rounds in an academic setting the justification for using an innovative procedure is more likely to be questioned, though even here the prestige of the attending physician may prevent rigorous criticism.
41. One court has held that the hospital has no duty to assure that a physician obtain legally effective consent from the patient. Fiorentino v. Wagner, 227 N.E.2d 296 (N.Y. 1967).
42. For a thorough analysis and account of the moratorium as a peer control device, see Swayzey and Fox, "The Clinical Moratorium: A Case Study of Mitral Valve Surgery", in Freund, ed. Experimentation with Human Subjects, 315-351 (1970).
43. Swayzey and Fox, however, might find the clinical moratorium to be more effective than I suggest. No doubt it has been effective in some instances, but without further evidence it does not appear likely to operate in most applications of innovative therapy.
44. For an account of the history and functioning of PSRO's, see Note, Federally Imposed Self-Regulation of Medical Practice: A Critique of PSRO, 42 Geo. Wash. 822 (1974).
45. Since innovative therapy by definition will depart from PSRO standards, PSRO review could discourage some applications of innovative therapy. This will depend on the willingness of PSROs to accept a physician's justification for departure from accepted practice. Conceivably, the frequency of boundary activities will not be affected.
46. The use of an innovative therapy is, by definition, an intentional deviation from standard practice.

Footnotes

47. Criteria for distinguishing innovative therapy from other forms of research would also be needed if one wishes to regard all innovative therapy as research, and then subject innovative therapy to control procedures different than those applied to all other forms of research.
48. See pp. 34-35, infra.
49. While the rules for experimentation need not include IRB review, given the history of federal controls on experimental activities it is likely that public policy will require some form of IRB review. What is unclear is whether IRB review will be required for all research with human subjects or just for research funded by the government or occurring in government funded institutions. Depending on the scope of the IRB requirement, and the means used to impose it, constitutional considerations may become relevant. See note 3, supra.
50. This assumes that IRB's actually do achieve these goals, though empirical data verifying their efficacy does not exist. It is particularly unclear whether IRB's will require innovative therapies to be applied in rigorously controlled circumstances, thus tending to turn each use of an innovative therapy into a formal clinical trial. While an IRB could have this effect, the author's experience on one IRB suggests that it may be unrealistic to expect significant gains in this regard.
51. For example, the PSRO legislation was challenged in an unsuccessful federal suit. Assoc. of Amer. Phys. and Surgeons v. Weinberger, 395 F.Supp. 125 (1975).
52. See note 4 supra. The government would face a more difficult challenge than it confronted in the PSRO litigation because the regulation of innovative therapy is not conditioned on receipt of federal funds.
53. See note 3 supra.
- 53a. If Medicare and Medicaid funded therapy was included in this category, the administrative problems discussed above would occur.
- 53b. The general assurances do not speak explicitly of innovative therapy, but rather commit the institution to adhere to the policies and procedures contained in 45 C.F.R. 46.1 - .22. 45 C.F.R. Sec. 4613(b) defines subject at risk in a manner that appears to include innovative therapy. See note 2, supra.

Footnotes

54. See Barber, Research on Human Subjects (1973); Gray, Human Subjects in Medical Experimentation 235-256 (1975). While both the Barber and Gray studies give little solace to IRB advocates, their findings may be reflect a temporary phenomenon that will pass with greater IRB experience and development of more effective procedures. The National Commission for the Protection of Subjects of Biomedical and Behavioral Research may generate data showing greater efficacy in both regards, or at least ways of increasing IRB efficacy.
55. Levine, Addendum to Boundaries Paper, September 25, 1975, p. 10a.
56. Id. at 18a.
57. Id. at 17a.
58. Id. at 10a, 11a.
59. Id. at 17a.
60. See note 50 supra.
61. 45 C.F.R. Sec. 46.2(b)(1).
62. Levine, "Boundaries Paper", prepared for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, pp. 6-7, 17, July 14, 1975.
63. Norton, "When Does an Experimental Innovative Procedure Become an Accepted Procedure," Pharos Oct., 1975, 161-162.
64. Francis Moore, for example, defines human experimentation "as either the intentional employment of normal human subjects as volunteers for physiologic experiments, or the study of patients (in a way that would not directly benefit them) to gather information on a disease or its treatment." "Therapeutic Innovation: Ethical Boundaries in the Initial Clinical Trials of New Drugs and Surgical Procedures", Daedalus, Spring, 1969, p. 502. Similarly, a subcommittee of the IRB of the Center for Health Sciences of the University of Wisconsin recently came up with this definition:

"any organized prospective process which seeks to secure new information from humans or about humans and/or which differs in any way from customary or generally accepted medical practice."

Footnotes

65. Robert Levine's definition also appears to exclude this possibility though elsewhere he acknowledges that such activity is research. See Levine, p. 10.
66. See Moore, op. cit., note 58, supra; Norton, op. cit., note 57, supra.
67. LaFave and Scott, Criminal Law 196 (1972).
68. Francis Moore, for example, expresses special concern for the safety of patients in the first use of a new drug or procedure. Op. cit., note 58, supra. However, the situations he discusses appear to involve an experimental intent, and thus would be subject to review on that basis.

Consider also the first heart transplant or use of a mechanical heart. A therapeutic intent in those situations cannot be denied, but it would be very difficult for Dr. Barnard or Dr. Cooley to maintain that they had no intent to gather knowledge about the procedure beyond the needs of the patient.

69. This appears to be the case currently with most instances of innovative therapy occurring in institutions receiving HEW funds. Few instances of innovative therapy are submitted for review, either before or after their use.
70. On the whole this statement appears to be true, though one can easily imagine therapies whose innovative or non-accepted status would be apparent to an observer, e.g., covering a patient with newspapers to treat cancer.
71. Robert Levine appears to reach a similar conclusion when he states:

"The definition of research provided in this paper is designed, in part, for the benefit of the professional who will wish to distinguish which of his activities may be viewed (by others) as research. He may be advised that, at some moment when he is considering performing some activity, he can consider whether his intent is in part or in whole research as contrasted with practice. In that case he may be advised further to express his intent in the form of a protocol and have it reviewed by an IRB. He may also be advised to conduct his consent negotiations with the prospective subject so as to make clear his intent to that individual."

Addendum to Boundaries Paper, 5a-6a, Sept. 24, 1975.

Footnotes

72. If the injury results from negligence, the subject might be able to recover damages. However, if there is no negligence, the subject is left bearing the cost of the injury.
73. Havighurst, "Compensating Persons Injured in Human Experimentation", 169 *Science* 153-157 (1970).
74. For discussion of the complexities of such a decision see Calabresi, The Cost of Accidents (1970); Havighurst and Tancredi, "Medical Adversity Insurance - A No-Fault Approach to Medical Malpractice and Quality Assurance", 51 Health and Society 125-168 (1973).
75. See the discussion of this point at pp. 11-14, supra.

THE BOUNDARIES BETWEEN BIOMEDICAL RESEARCH INVOLVING HUMAN
SUBJECTS AND THE ACCEPTED OR ROUTINE PRACTICE OF
MEDICINE, WITH PARTICULAR EMPHASIS ON
INNOVATION IN THE PRACTICE OF SURGERY

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In the introduction of Levine's thoughtful position paper, he emphasizes the fact that it is fortunate that sharp definitions between the boundaries of biomedical or behavioral research and accepted and routine medical practices are not required, a fact of much importance. As one pursues this subject, it becomes evident that there is no dividing line which can be consistently agreed upon by any group of authorities on the subject. In fact, it is generally recognized that such an arbitrary division is simply impossible, at least if determined on a rational basis. Therefore, an objective of an appraisal of this subject might be the development of a series of approaches leading to an improved and more complete understanding of this increasingly important issue.

At the outset, it can be stated that there are two parts of the spectrum which are definite: (1) those diagnostic and therapeutic areas in medicine about which the overwhelming majority of authorities would agree that the test or treatment is established beyond reasonable doubt. Fortunately, this portion of the spectrum in medical practice comprises the vast majority of the field today, and clearly this is true as applied to the surgical disciplines. At the opposite end of the spectrum are those studies which are clearly experimental and are being pursued for the acquisition of basic knowledge without any intent to suggest by implication or fact that the patient will immediately benefit. Again, the first portion of the spectrum represents a large area of daily endeavor and the latter a much smaller one. Between these two positions, there is a definite "gray zone" in which it is difficult to classify objectively the diagnostic test or the therapeutic program as accepted practice versus experimentation.

One point which can be appropriately made is the fact that the role of the intent of a given procedure might be profitably minimized, since it is almost always impossible to prove this point, certainly from a legal point of view. Moreover, insofar as an individual patient is concerned, it might be said that there is often little difference in the approach to therapy and an experiment since in modern medicine one should outline in detail the benefits and risks in both situations. Moreover, quality control of patient care is and should be monitored by peer review groups, whereas human investigation should be controlled by institutional panels designed to review each protocol with membership of the panel broadly chosen, including informed members of the laity. In this connection, the comments of Philip Handler, President of the National Academy of Sciences, bear repetition. He succinctly summarizes the present status of human experimentation as follows: "It is no longer possible for an isolated investigator to go off on his own and simply do as he pleases. He is now accountable to his colleagues, in advance, before he may undertake any proposed experiment. Indeed, that very process has increased the sophistication of current medical research." Ultimately, all relationships between physicians and patients rest upon a personal agreement between the two parties. While it is recognized that in many instances such relationships between physicians and patients have eroded by comparison with the past, it is equally important to stress the need for a return to this important and much to be desired relationship.

In Dr. Levine's comments concerning "patients and subjects" and their relationship on the one hand to a health care professional and on the other as

an individual who is to be observed or experimented with by an investigator do represent the situation at the two ends of the spectrum, but a significant number of persons fall into an intermediate category difficult to define. His comments on the natural history of various diseases are also quite significant since it is such data that provide the physician and surgeon with the appropriate facts to discuss with the patient, the problem, and frequently the need for experimentation in an effort to improve both the quality of life as well as its length. The thoughts expressed about fiduciary relationship of experimental studies are also well taken. While monetary reward is often significant in terms of separation of therapy from pure research, such is not an adequate or appropriate classifying device.

Every physician, and indeed many informed laymen, recognize that most of the advances in medicine have derived from what must be defined as "human experimentation." The surgeon generally insists first upon the performance of new operative procedures in the experimental animal with careful attention being given the clinical course as well as the biochemical, physiological, and pathological changes which follow. Nevertheless, when the operation is first performed on humans, by definition it must be termed an experiment, although one being done with sound preliminary knowledge. Under these circumstances, it is imperative that the patient be fully appraised of everything that is known and of the risks involved. Obviously, informed consent in the fullest meaning of the term is essential.

It is also recognized that many medical advances have been made as a result of totally healthy human volunteers who have nothing to gain except

personal gratification, at least immediately, from the scientific information that might be derived from an experimental study. For example, the entire field of the transplantation of human organs has been greatly advanced by those healthy donors willing to undergo an operation for removal of one of the two normal kidneys to be transplanted into a patient with life-threatening renal insufficiency. It is apparent that while the total risk of the operation upon the donor is low, nevertheless it is real and could indeed in rare instances be life-threatening. Despite this fact when the need arises, it is usual for a volunteer to be forthcoming and with full realization of the potential hazards which might occur.

A classic example of the advantages to mankind from human experimentation is summarized in the following historic citation: "Professor Forssmann: As a young doctor, you had the courage to submit yourself to heart catheterization. As a result of this, a new method was born which since that time has proven to be of great value. It has not only opened new roads for the study of the physiology and pathology of the heart and lungs, it has also given the impetus for important researches on other organs." This short, yet profound, introduction of a historic contribution to medical science comprised the citation to Werner Theodor Otto Forssmann when he was awarded the Nobel Prize in Medicine in 1956. The interesting feature of this monumental achievement is the fact that as a 25 year old intern in surgery this pioneer, after repeated trials of cardiac catheterizations in the cadaver, introduced a catheter into his own arm vein and passed it into the right ventricle of his heart. Despite the

fact that he had approached a member of the faculty and a fellow intern to assist with the procedure, both refused to assume any responsibility for the experiment.

In current surgical practice, it is well recognized that the majority of operations performed in this country are those which are widely accepted as standard practice with results of proven efficacy. Thus, the removal of the appendix for acute inflammation, removal of stones from the common bile duct in obstructive jaundice, the removal of most neoplasms (especially those without evidence of metastases), and the surgical drainage of purulent abscesses are typical examples. However, many procedures might appropriately be classified in an intermediate category including operations such as intestinal bypass operations for control of obesity and for hyperlipidemias.

In the recent past, much emphasis has been given the subject of revascularization of the heart for myocardial ischemia (coronary arterial bypass procedures). While it is clear that the non-operative management of angina pectoris and its complications is often effective, nevertheless in many instances, this form of therapy leaves much to be desired. The development in the past decade of the coronary bypass procedures has led to the widespread adoption of this technique with an estimated 50,000 or more of these operations being done annually in the United States. Nevertheless, justifiable controversy continues concerning the indications for such therapy and indeed of the long-term results. On the basis of the data available, it is generally accepted that the relief of pain is achieved in approximately two-thirds

of the patients and an additional 15 to 20 percent receive partial relief of anginal discomfort. One of the most desired results of this operation is the prolongation of life, and upon this point there is conflicting evidence. However, at this point in time the preponderant view supported by accumulated statistics indicates that the operation does not extend the length of life when compared with appropriate controls managed medically. For example, the Veterans Administration Hospital system has recently completed a five year randomized study of a series of patients with documented angina pectoris due to significant atherosclerotic obstructing lesions in the coronary arteries. All patients were reviewed by a cardiological and surgical panel in the cooperating centers, and it was agreed that each was an appropriate candidate for surgical treatment by contemporary criteria. The plan for the randomized study was carefully reviewed with each patient and explained in appropriate detail. Following this, an envelope was opened which committed the patient either to medical or surgical therapy. Thus, among the patients in the study, half were operated upon with the performance of a bypass graft and the remaining half were managed by customary medical (non-operative) therapy. The investigators chose not to study the relief of anginal pain in these patients, but rather directed their interest toward longevity. It was interesting that the life expectancy of these patients was the same in each group, with the exception that those patients who had significant stenosis of the left main coronary artery had an improved life expectancy following surgery. (In most series, obstruction of the left main coronary artery comprises approximately 10 percent of the total

patients undergoing coronary arteriography for angina pectoris.) Thus, while this operation is widely employed, attention should be directed toward the known facts concerning the benefits which can reasonably and objectively be expected from the procedure.

Every surgical procedure is in a sense an experiment, since one cannot predict with accuracy the development of postoperative complications which may ensue, as for example the appearance of a wound infection. In fact, in his original report of the cardiac catheterization upon himself, Forssmann mentioned that he developed a wound infection in the self-made incision.

Thus, from a surgical point of view, innovations are being made daily as an individual surgeon finds improved results with specific changes in operative technique. While these may be minor, it should be noted that they often arise in specific situations not previously encountered and call for a decision to be made immediately in order to prevent a perilous outcome. Since the patient is anesthetized and usually cannot be safely awakened, total informed consent is not possible. An example of this type is the pioneering contribution of Dr. Bertram M. Bernheim. A student of the noted surgeon, William S. Halsted, in 1915 Bernheim operated upon a patient with a painful and expanding aneurysm of the popliteal artery which threatened to rupture. Prior to operation, he had demonstrated that temporary occlusion of the femoral artery above the aneurysm produced clinical signs of ischemia in the leg distally. Therefore, he knew in advance that it would be necessary to leave a portion of the aneurysm to allow continuity of blood flow from the femoral artery above into the popliteal artery below

otherwise gangrene of a portion of the leg would ensue. However, at operation the aneurysm was so thin-walled and the tissues of such poor quality that none of it was available for restoration of continuity of the artery above with that below. Therefore, rather than simply ligating the two ends of the arteries, which were quite far apart and not available for direct anastomosis, he removed a segment of saphenous vein and used it as a substitute. Dr. Halsted, in commenting upon this pioneering achievement, called it the "ideal operation for the treatment of a popliteal aneurysm." However, this was not predictable beforehand but represented a reasonable alternative to what otherwise would have been a disastrous result, that is, amputation of a limb. Obviously, Dr. Bernheim was willing to assume the responsibility for his action, and it is clearly an example of appropriate judgment and action in an admittedly difficult situation.

Summary

In the consideration of boundaries between biomedical or behavioral research and the accepted routine practice of medicine, it is apparent that while the establishing of such distinctions is desirable, it is nevertheless extraordinarily difficult. In the surgical sciences, innovative changes are both essential and desirable in daily practice. Moreover, in the clinical setting of surgery, it is not always possible to predict the situation which will be encountered and therefore to have the opportunity to provide total informed consent. Nevertheless, the key feature of both modern therapy and research is based upon a detailed and frank exchange between the physician or investigator and the patient. While it is important to define the intent, from a legal point of view

such is exceedingly difficult to prove. In the vast majority of instances, the most appropriate means of monitoring quality control in medicine is by the peer review mechanism, whereas monitoring of human investigation is best achieved by review panels broadly composed to specifically evaluate and decide upon each protocol proposed. Clearly, human investigation in the surgical disciplines, as well as in all of medicine, is essential if the advances characteristic of the past several decades are to continue.

WHAT PROBLEMS ARE RAISED WHEN THE CURRENT DHEW REGULATION
ON PROTECTION OF HUMAN SUBJECTS IS APPLIED TO SOCIAL
SCIENCE RESEARCH?

Richard A. Tropp

What Problems Are Raised When the Current DHEW
Regulation on Protection of Human Subjects
Is Applied to Social Science Research?

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Question Presented

What amendments, if any, should be made in the current DHEW regulation on "Protection of Human Subjects" (hereinafter, "Part 46") in order to facilitate the application of the regulation to social science research? What issues and problems are raised by application of Part 46 as it stands to such research?

It is assumed, for purposes of this analysis, that the expression "social science research" includes behavioral research conducted outside of the clinical psychological setting. It is unnecessary for purposes of the analysis, and for drafting possible amendments to Part 46, to reach the issue of where "social science research" is discontinuous with "behavioral research"--although it is precisely this thorny boundary question which has been the focus of the greatest wrangling between the agencies within DHEW which have been discussing possible amendments to the regulation.

Background

Under the gun of imminent passage by Congress of the National Research Act, the Secretary of DHEW on May 22, 1974 signed a regulation on "Protection of Human Subjects" for Federal Register publication on May 30. The regulation was the product of an extended drafting process by NIH staff, assisted by DHEW General Counsel staff assigned to, and housed within, NIH. The Department's other line agencies--the Office of Human Development, the Social and Rehabilitation Service, the Office of Education, and the National Institute of Education, inter alia--were not involved in that drafting process; the staff offices within the Office of the Secretary were not involved until very late in the game.

Consequently, the regulation came as a great surprise to the rest of the Department, which was collectively taken unaware not only by the applicability of Part 46 to all Department activities, but also at finding out that the Guidelines preceding Part 46 had, on their face, applied to the other agencies all along. At the time Part 46 was published, substantial differences had arisen within the Department--and, under the deadline pressure, had not been resolved--on the applicability of the regulation to non-biomedical research and to demonstration and service delivery programs.

Notwithstanding the absence of consensus within the Department, the regulation was published in order to meet the perceived needs of the Congressional conference committee then considering the National Research Act (now P. L. 93-348). It was understood within the Department--and

alluded to in the preamble to the regulation--that discussion and negotiation would proceed among the agencies and the OS staff offices in order to construct a regulation appropriate to social science research and to operating programs. It was intended by the parties involved in the decision to publish the regulation, for example, that income maintenance and health services financing experiments not be constrained by a regulation written with biomedical research as its conceptual framework.

Extended discussion among the affected organizations within DHEW has made it clear that the agencies generally are responding to the regulation by ignoring it, as they did the Guideline which was its predecessor. The discussion has, however, begun to educate policy-level agency staffs on their responsibilities under the regulation, and has generated reflection on how the regulation might be optimally structured so as to protect subjects involved in non-health-services research. There has been some clarification of precisely what questions Part 46 raises, and whose interests each question affects.

This analysis will identify those major questions, and will suggest some alternative remedies available to the Commission if it should choose to consider amending Part 46 in order to maximize its applicability to all Department research.

1. Explicit Coverage of Social Science Research

Although social science research is implicitly covered by the Applicability section of Part 46, the history of the regulation has caused many, if not most, grantees and contractors to assume that only biomedical and clinical psychological research funded by the agencies within the "H" part of DHEW is covered. Other agencies within the Department see Part 46 as being ambiguous on whether human subjects at risk arising from social science research are protected.

The language of the informed consent requirement, which seems to many grantees and contractors to be particularly tailored to biomedical research, reinforces their predilection--and that of agency staff outside the "H" organizations--to assume that the regulation simply does not apply to them.

In order to send a clear signal to grantees and contractors, and to all agencies of the Department, that all DHEW-funded research is to be covered by Part 46, perhaps the regulation should specify that its scope of coverage incorporates social science research. Alternatively, perhaps the preamble to the regulation ought to specify that the ambiguous Congressional language "behavioral research" should be construed to encompass all non-biomedical research funded by DHEW.

2. Coverage of Intramural Research

For most of its history, Part 46 has not covered human subjects involved in research conducted by employees of the Department (intramural research), only research conducted outside DHEW under grants and contracts (extramural research). NIH has long protected subjects of its own intramural research, but no other agency of the Department has had its own procedures to

regulate intramural social science research and behavioral research conducted outside of a clinical psychological setting.

In August 1975, as an afterthought to the regulation on fetal research, a new subpart was added to Part 46 in order to achieve the end of regulating all DHEW intramural research. That new subpart tries to say that the substantive standards which Part 46 applies to extramural research will hereinafter apply to all DHEW intramural research as well, but that each agency may--emulating NIH--set up its own internal procedures to enforce the application of those substantive standards. The intent was to permit "H" to retain its current internal procedures, while compelling the other agencies to establish procedures which they presently lack.

Assuming that this approach is the optimal one, the new intramural research subpart is at best unclear on just precisely what it is that the agencies have to do. Since it is not incorporated into the main body of the regulation, it is generally unknown within DHEW. At the minimum, it would seem useful for the substance of the new subpart to be transferred to the Applicability section of Part 46, and for it to be rewritten so as to be specific in its guidance to agency heads on what it is that they have to do tomorrow as a consequence of this new wrinkle in the regulation.

It may be, however, that the approach of many different agency procedures is not the optimal one, on the ground that it is neither seemly, nor consistent with the intent of independent review of research proposals, for employees of an agency to review assurances of compliance from other employees of the same agency.

Under the section Submission of Assurances (§46.4 of Part 46), assurances of compliance with the regulation must be filed by grantees and contractors with the Department, and must be approved as consistent with Part 46 prior to funding of the research. Perhaps that section should be amended to require that when agency staffs propose to conduct intramural research, assurances of compliance must be filed with, and reviewed by, one of the staff offices within the Office of the Secretary or, alternatively, a board of outside advisors to the Secretary. Research involving risk of physical injury, and research conducted in a clinical psychological setting, could remain within the bailiwick of H's intramural review procedures.

Establishing a procedure within OS to review agency research for compliance with the regulation, and requiring that intramural research must receive OS compliance approval, would maximize uniformity across the Department of protection of subjects involved in behavioral and social science research. A body of administrative case law could be established to which agencies would turn for guidance. An OS staff office procedure, or an outside board, would be of assistance to an agency head caught in cross-pressures on whether he should authorize an ethically dubious intramural project.

It would be useful for the Commission to examine (i) whether it is satisfied with the current approach of many different agency internal procedures enforcing one uniform substantive standard; (ii) if so, whether it is satisfied with the extent to which the new subpart clarifies for agency

heads what is to be construed as "procedural" (and therefore subject to variance) and what as "substantive" (and therefore not subject to discretionary implementation by an agency head), and whether the language is, generally, sufficient guidance to agency heads and research staff; and (iii) if not, what alternative, possibly including OS staff or advisory board review, would be most likely to ensure substantive compliance with Part 46 by Department employees who conduct intramural research.

3. Protection of Individuals at Risk Who Are Not "Subjects" of Research

In social science and non-clinical behavioral research, persons may be placed at risk of harm even though the research does not generate data about their behavior, and is not intended to intervene in their lives. The researcher never encounters them in the course of administering his research project, but he may be unable to prevent external diseconomies which accrue to them from his experimental intervention or from the data collection process. For example,

- (i) Apartment rents may be driven up in neighborhoods which house a threshold mass of housing allowance experiment subjects. The effects of the price rise will be felt by nonparticipant neighbors of the subjects, and by those who seek to move into the neighborhood.
- (ii) Labor supply prices may be driven either up (if subjects opt out of the labor market) or down (if subjects remain in the labor market, but become willing to take much lower-paying jobs as long as they also obtain an income supplement with an acceptably low marginal tax rate on earnings) in the labor market which contains a threshold mass of income maintenance experiment subjects. Depending upon which way prices go, either nonparticipant employers or nonparticipant competing employees will be financially harmed.
- (iii) A police deployment or patrol pattern experiment may transfer some kinds of crime from one neighborhood to another, thereby benefiting some nonparticipant individuals and harming others.
- (iv) A health insurance experiment may increase the price, and decrease the supply, of some scarce medical resources in a particular area. At the extreme, a nonparticipant individual may die as a consequence of being priced out of the market for a scarce life-saving resource, which goes instead to an experimental subject whose purchase of the resource is subsidized by the research.

The current regulation does not extend its protections to anyone who is not directly a subject of research. If the regulation is to be applicable to all behavioral and social science research, arguably the definition of "subject at risk" (§46.3) should be amended in order to create a new class of persons at risk who are protected even though the researcher does not perceive or treat them as subjects. There is no such class in the current regulation because the definition of "subject at risk" was drafted within the conceptual framework of a biomedical research model.

Some DHEW attorneys have argued that nonparticipants at risk arising from social science research should not be protected by Part 46, or should not be as rigorously protected, since the Department owes them no duty under current law. Case law has, in contrast, established clear responsibilities by the biomedical researcher toward his subject. Were Part 46 to be amended to extend those responsibilities to the nonparticipant at risk, DHEW would open itself, and its research contractors and grantees, to novel legal liability.

It is quite true that the case law of informed consent has thus far been limited to factual contexts involving face-to-face contact between a biomedical researcher and his subject. It does not follow from that, however, that the courts will find a nonparticipant at risk to have no claim. The matter has simply not risen to judicial attention. It may readily be argued that a court will soon find a plaintiff nonparticipant at risk to be, with respect to social science research, in the same position as the subject of biomedical research, and therefore to be entitled to protections analogous to those of Part 46.

Even assuming that judicial remedy would be restricted to subjects who have chosen to participate in research, so what? The limitations of current law need not constrain either the Secretary or the Commission in parsing out what kinds of protections are ethically--if not legally--owed to nonparticipants at risk arising from research funded by DHEW. The current regulation, in fact, offers protections to subjects which exceed the protections upon which the judiciary has reached consensus. The Commission can recommend, and the Secretary can make, new law.

It has also been argued that creation of a new class of administratively protected nonparticipants at risk would be detrimental to some biomedical research, since family members and friends of subjects could claim harm solely by virtue of their relationship with a subject who is actually at risk of harm arising from his participation in an experiment. Assuming that it is undesirable to compel biomedical and behavioral researchers to seek the informed consent of family members and friends who may be at risk solely because of their contact with a research subject, the problem can be avoided by incorporating into the regulation a new definition of "physical injury" and, perhaps, of "psychological injury". The definition could specify that injury cannot be claimed, for purposes of invoking the protections of Part 46, solely by virtue of a person's family or other relationship with a research subject.

Were that definition written into Part 46, creation of a new legally protected class of nonparticipants at risk would not constrain biomedical research. It would, however, protect nonparticipants unwittingly at risk arising from social science research.

4. Should Participants in National Demonstration Programs and Service Delivery Programs be Covered by the Regulation?

Part 46 presently extends its protections to participants in all "research, development and related activities" funded by DHEW. "Development and related activities" is undefined, and may be construed to cover non-biomedical demonstrations and service delivery programs. Were the agencies to take the regulation language seriously, a number of interesting problems would follow:

- (i) National demonstration programs such as Head Start and youth services systems would be required to have each grantee create an institutional review board. In the politically supercharged community environment within which the grantees function, the constitution of such a board--and its power to constrain a program director--might well become political footballs tossed between community groups struggling for legitimacy and power. That is a cost arguably worth incurring when there is more than minimal risk to a child, but is it still worth it when the IRB is to be established--and consent sought from every parent--simply because Head Start and youth service systems depart from the established and accepted methods of reaching children?

In the eyes of managers of these and a number of other non-biomedical national demonstration programs, the prospect of creating an IRB and seeking consent from every participant's guardian is an explosive, and unnecessary nightmare.

- (ii) On its face, the regulation would also require consent and IRBs of every grantee who conducts a service delivery program which departs from established and accepted methods of meeting participants' needs--even though the risk is marginal, and even though the program is not perceived by DHEW as either an experiment or a demonstration. Community mental health centers would be required to conform to Part 46, for instance, as would schools which receive compensatory education funds under Title I of the Elementary and Secondary Education Act.

Conformity with Part 46 by these kinds of programs raises, on a national scale exceeding that of demonstration programs, the prospect of widespread community infighting triggered by allegations of marginal risk.

Although the non-"H" agencies have striven to avoid applying Part 46 to national demonstrations and to service delivery, it seems inescapable from the face of the regulation language that they will have to begin doing so. If the Commission and the Secretary deem that to be a desirable outcome, it would be helpful to agency managers if Part 46 were amended to make it explicitly clear that the intent is to include all DHEW grantees and contractors, not only those engaged in research and development.

Alternatively, perhaps the regulation should be amended to specifically exclude from its protections persons receiving benefits from national demonstrations and from service delivery programs, save for biomedical national demonstrations which--like clinical trials or HMOs--may involve risk of physical harm to participants.

5. Should the Regulation Protect Subjects and Others Against Injury Suffered by Them in Their Capacity as Members of a Group?

Part 46 protects a subject at risk of "psychological injury" or "social injury", without defining those expressions. Absent a definition of "psychological injury", someone may claim risk of injury if the interests of his racial, ethnic, religious, economic, or community group seem to conflict with a particular research project--even if there is no other risk of harm to the individual separate from the alleged harm to his group. Moreover, someone may claim risk solely because he is a relative or friend of someone who has actually been injured (has become depressed, for instance, or has lost self-esteem) by research.

With "psychological injury" already a component of the definition of risk, the additional expression "social injury" opens a Pandora's box of allegations of injury to an individual in his capacity as member of a group or community. If the only risk alleged with respect to a particular research project is injury to a group or community, a large dose of political hoopla will doubtless accompany the establishment of an IRB and the submission of a general or special assurance under the regulation.

Given the inevitable political conflict, the question is whether allegations of group or collateral psychological injury should be sufficient to trigger the protections of the regulation, absent a separately identifiable risk of individual injury. If not, the expression "social injury" should be stricken from the regulation, and a new definition of "psychological injury" should be added to Part 46, specifying that risk of such injury refers only to that injury which a person may suffer in his individual capacity, and not merely in his capacity as a relative or friend of a research subject, or as member of a group or community.

6. Should Risk of Financial Injury be Covered?

Part 46, drafted within a biomedical conceptual framework, contains no reference to risk of financial injury. The regulation consequently fails to protect persons participating in income maintenance, health insurance, and other social science research funded by most of the agencies in DHEW.

Assuming that Part 46 is to protect persons at risk in all research conducted or supported by DHEW, risk of loss of present or anticipated assets or income ought to be incorporated into the definition of risk.

7. Risks Arising from Publication or Policy Application of Research Results ^{1/}

Social science research is sometimes met with interest group or community protests on the ground that publication of a research conclusion (cf. Arthur Jensen's research), or government policy changes based on the research results (cf. the income maintenance experiments, particularly in Gary, Indiana), will be harmful to the group or community as a whole, although specific risks to specific individuals cannot be identified.

The regulation is silent on whether such alleged risk triggers its

protections, but a number of grantees and contractors have run up against the question. Where it has arisen, it has been highly politicized.

If indeed we do want such risks explained to subjects (in, for instance, educational performance research which will compare ethnic or economic group performance on IQ or achievement tests), and considered by IRBs, then that intent should be made explicit in the definition of risk. If not, it would be helpful to those conducting field social science research if language were added to the definition of risk providing that, except as research results pertain to a named or identifiable person, "risks arising from publication or policy application of research results" will not be deemed sufficient to trigger invocation of the protections of Part 46.

The exception for research results pertaining to a named or identifiable person will protect the subject of biomedical or clinical psychological research whose case history has been taken, and whose privacy would be invaded by publication of material from that case history.

8. Must All Research Procedures, and the Purpose of Research, be Explained to the Subject?

Part 46 presently requires that all research procedures be explained, in all types of research, regardless of whether particular procedures do or do not cause a subject to be at risk. It is also required, as part of the informed consent process (§46.3(c)), that purposes be fully explained to the subject, regardless of whether particular purposes are material to his determination of risk to him.

DHEW's Guidelines until 1974 did not specify that purpose be disclosed, and the American Medical Association's principles still do not. Disclosure of purpose is, however, required in the Nuremberg Code, the Declaration of Helsinki, and the World Medical Association Code.^{2/} Several of the participants in the recent Brookings conference on social experimentation went out of their way to suggest that "There should be no ethical responsibility to inform subjects in analytical detail about the intent of the research,"^{3/} and

- (i) "/T/o disclose the purpose of the research may jeopardize the scientific validity of the results. This is certainly true in social science research since it is concerned with the behavior of subjects....This behavior may be influenced not only by the pure treatment, but by...the subject's perception of the experimenter's expectations. To tell a subject in a health insurance experiment that you will be interested in how he utilizes medical services may well bias his response, particularly if the explanation is followed by frequent questions about health."^{4/}
- (ii) "The most appropriate course /for the researcher, in obtaining informed consent from a subject/ seems to be to emphasize the important facts that will influence their decisions to participate...."^{5/}

(iii) "/E/xperimenters have no moral obligation to give subjects more information than they need to act in their long-run best interests, particularly if there is a risk that subjects might respond differently...."6/

(iv) "The only thing he /the researcher/ can do is...give the subjects all information relevant to their own decision to participate."7/

The problem is that explanation of research purpose, and of some research procedures, will skew research results in many types of behavioral and social science research, because the subject's behavior will be affected by his acquisition of the knowledge. Whether or not a subject takes a job while he is receiving benefits under an income maintenance experiment, for instance, may well be affected by his knowledge that the major purpose of the experiment is precisely to discover whether or not the income supplement affects his labor market decision.

What the Brookings conference participants generally argue is that research purpose and procedures should be disclosed only insofar as the information is material to the subject's decision process as to whether or not he will participate in an experiment, and on what terms. An alternative formulation is to require explanation only of those research procedures which may cause an individual to be at risk, including identification of any procedures which are experimental. If only information material to the calculation of risk is disclosed, perhaps research purpose may be omitted most of the time in securing informed consent.

Whether the Commission elects to adopt the Brookings conference consensus (explain what is material to the subject's decision), the risk test (explain only what is material to determination of risk; omit explanation of purpose entirely if it is not), or a third alternative, this is an issue which badly needs examination. As currently drafted, the language of the regulation's definition of informed consent is inappropriate to non-biomedical research. It erects for behavioral and social science research a disclosure requirement which goes far beyond what is necessary to enable a subject to make rational choices in the informed consent process, and it does so at the cost of skewing research results.

Practically, what seems to be happening now is that DHEW agencies, including those agencies within "H" which conduct and support behavioral research, simply ignore this requirement, or effectively waive it through an inappropriate use of the regulation's modification clause (§46.10(c)). The seemingly stringent requirement for complete disclosure of procedures and purposes has the effect, in the real world of research, of protecting subjects much less than a moderated, enforceable requirement would.

9. Must Benefits Expected from the Research, and Alternative Procedures, be Explained to the Subject in Social Science Research?

Part 46, within the framework of the biomedical model, currently requires explanation to the subject of benefits which he may expect from the research, and of "appropriate alternative procedures that might be advantageous to the subject".

Explanation of benefits, like explanation of research purposes and of some research procedures, may skew social science research results by affecting the subject's behavior, particularly if the subject is in a control group and understands the difference between the benefits which he is receiving and those which accrue to members of an experimental group.

In biomedical research, there may be standard and accepted procedures which are real alternatives for a subject in research. In social science research, no such beneficial alternatives usually exist, while an infinity of benefit permutations (how much money and what kinds of services we provide in an income maintenance experiment, for instance) may be available. Explanation of all possible benefit packages would burden the researcher to no gain by the subject, and may cost the researcher loss of subjects.

Perhaps the informed consent definition should be amended to provide that all benefits and alternative procedures need be explained only, as in biomedical and some behavioral research, when a standard and accepted therapeutic option is available. The same requirement could be maintained for those types of research to which it is material, while a needless burden would be removed from social science researchers.

Alternatively, perhaps benefits and alternative procedures should be explained whenever a standard and accepted option is available (when, for instance, the subject in a housing allowance experiment could obtain a higher subsidy from another program, were he to withdraw from the experiment), irrespective of whether the option is "therapeutic" within the biomedical and clinical psychological models.

10. Should Possible Breach of Confidentiality of Data Collected in Survey Research be Considered a Risk Which Triggers the Protections of This Regulation?

Survey research raises most acutely a problem inherent in all data collection: is breach of confidentiality of the data collected to be considered a risk which triggers invocation of Part 46? The current regulation is silent on the issue, permitting the inference that breach of confidentiality may be construed as an "attendant discomfort or risk reasonably to be expected" (§46.3(c)). It follows, if the inference is made, that the survey researcher must, before he begins to ask his questions, describe in detail the various ways in which respondent confidentiality may be breached, and obtain the respondent's formal informed consent.

If the research investigator has to proffer a lengthy explanation of the risk and obtain a consent form, the probability is high that he will lose many of his chosen respondents, thus making it difficult or impossible for him properly to randomize or stratify his sample. Some or many of those whom he does not lose will prove less than frank in their answers, destroying the utility of his data.

Breach of confidentiality under judicial or other governmental subpoena definitely is a risk, as David Kershaw recounts in the Brookings conference in noting that a grand jury, at least two welfare departments, the General Accounting Office, and the Senate Finance Committee attempted to secure confidential data from the New Jersey income maintenance experiment (mostly in order to track down fraudulent welfare recipients).^{8/} There is, moreover, the simple danger that gossip by survey research employees engaged in data collection or analysis will harm a respondent.

The effect of rigorous imposition of the informed consent requirement in survey research can, on the other hand, destroy the utility of the research design and instruments:

"In short, informed consent procedures are going to make social research inaccurate. The amount of error is unknown, and will remain forever undeterminable....The study clearly demonstrates that the inclusion of informed consent procedures in some types of social science /survey/ research will lead to serious loss of data and /to/ response bias in some circumstances."^{9/}

In order to minimize the effects of data loss and response bias, moreover, it is--as Donald Campbell has noted^{10/}--essential for data to remain available for sample reinterview. This is particularly true when surveys are focused on service delivery by states and units of local government, and when there is a need for Federal auditing of the data in order to ensure that services have actually have been delivered as reported. Data verification, whether for these purposes or simply to check interviewer honesty and competence (Campbell's concern), imposes additional risks of breach of confidentiality which, if explained to the respondent, will induce further respondent loss and response bias.

One way to handle the problem may be to amend the definition of informed consent, in Part 46, to provide that if the survey research investigator has established measures to ensure confidentiality of collected data, and if he has tersely informed the respondent that the risk of breach exists and that the measures exist, the risk of breach of confidentiality will not be considered an "attendant discomfort or risk reasonably to be expected", and will therefore not trigger the protections of the regulation. What would be required of the survey researcher is that steps be taken to actually protect confidentiality, and that the subject be informed that such steps have been taken.

The effect of such an amendment would be, assuming that the researcher met the prerequisite conditions, to specify that the researcher need not explain in detail what each of the risks of breach are, and need not obtain formal informed consent as a prerequisite to asking survey questions.

Alternatively, the Commission may wish to make such an amendment applicable to all social science research, or all research funded by DHEW, not merely survey research.

Whatever the resolution of the problem, there is a need for it to be addressed. Abundant feedback from the survey research community indicates that it is confused as to its responsibilities under Part 46, and that it is generally reacting to that confusion by ignoring the regulation. Whatever the treatment of the confidentiality problem in survey research is to be, there should be language specifically addressed to it in the definition of informed consent or, alternatively, in the definition of risk.

11. Should Waiver of the Informed Consent Requirement be Permitted Under Exceptional Conditions in Social Science Research?

The present regulation provides (§46.10(c), Documentation of Informed Consent) that there may be modification of the form of documentation that informed consent has been given by subjects in a particular research project. Reports from "H" staff supervising behavioral research, other DHEW agency staffs, and grantees and contractors indicate that this "modification" clause is frequently used to effect a waiver of some of the elements of informed consent. This has been done when it has appeared that a particular research project could not proceed if the whole informed consent procedure were to be implemented--if, for instance, all procedures employed in the research were explained to subjects whose behavioral responses were to be measured by the research.

It is clear that the modification section needs tightening up to ensure that it cannot be used as an invisible justification for abdication of some elements of the informed consent requirement.

Widespread use of the modification clause to avoid some of the substantive protections of the regulation, however, does suggest that there may be circumstances in which the Secretary, the funding agency, or an outside advisory board should be empowered, pursuant to strictly drawn criteria, to waive some of the elements of informed consent for particular research projects. For example,

- (i) What if, as in a housing allowance or a police patrol experiment, it is impossible to identify all of the nonparticipants at risk arising from the experiment? Alternatively, what if they can be identified only at prohibitive cost?
- (ii) What if they can be identified, but it is impossible to obtain consent at reasonable expense from a large non-subject population at risk, with whom the researcher would not ordinarily establish contact in the course of the research?
- (iii) What if, as in unobtrusive measures research, there is a research design need to prevent individuals from knowing that the research is being conducted, in order to avoid skewing of otherwise natural behaviors which the researcher seeks to observe?

In social science research in which such circumstances are present, and perhaps in other circumstances as well, we may want to empower the Secretary or another party to waive some of the elements of the informed consent requirement, provided that:

- (i) The waiver would apply only to nonparticipant persons at risk arising from the research in question, not to subjects who are identifiable ex ante and from whom data is collected. In a housing allowance experiment, for instance, waiver might be granted with respect to neighbors whose rents may be affected by the experiment, but not with respect to subjects who actually receive the allowance.
- (ii) Waiver would be granted only upon a showing that it is "demonstrably infeasible" to obtain informed consent from a specified nonparticipant population, on the ground that one of a number of narrowly specified triggering conditions exists. The regulation could specify that the expression "demonstrably infeasible" (or some analogue) be strictly construed, and that the criteria--the conditions precedent--be very strictly construed. It could be specified that the intent of the strict construction is that waiver be infrequently approved.
- (iii) Waiver would be granted only under the condition that the information withheld be given, where the persons at risk are identifiable, to the affected persons in a debriefing after the research procedure has been completed.
- (iv) Waiver would be granted only under the condition that the research investigator attest in writing that the risk to nonparticipants reasonably to be expected from the research is deemed insubstantial in probability and in magnitude.

In the event of waiver, and if the nonparticipants at risk reside principally within a particular unit of local government or, alternatively, within a single state, perhaps the regulation should require surrogate consent by an official of the local or state government. This proxy for individual agreement would be intended to provide local control over the acceptability of risk to non-subject persons, and to maximize the willing participation of the community affected by the research.

Given the realities of local government, the probability is that members of the community disinclined to have their local government consent to an experiment will be able to have their way, even though their numbers be few--simply because they will care much more about the research than those community members inclined to permit proxy consent to be given to a particular research project. Those who care most intensely about an issue are generally able, absent similar intensity of feeling on the other side of the issue, to prevail at the local government level.

11/

Several of the Brookings conferees indicated their enthusiasm for surrogate local government consent as a means for protection of

non-subject populations at risk from research which affects an entire community, labor market, or commodity (such as housing, or hospital services) market. There were some caveats, however:

"For large-scale social experiments...it is unlikely that any group with a prior definition will ever be quite unanimous in its consent--or unanimous without what some commentators have been calling 'undue inducements.' (Or, as probably happens, a majority coerces the minority to shut up and sign up, or a minority coerces the majority to do so.)" 12/

"This extension of the consent principle /proxy consent by elected representatives of affected nonparticipants/ may not always have the intended effect. When representatives of the Department of Housing and Urban Development took their proposal for a housing allowance supply experiment before the city council of Green Bay, Wisconsin, and carefully explained that local house prices might increase as a result, the council's immediate response was eagerly to calculate the implicit rise in property tax revenues." 13/

Surrogate consent will be pernicious and arbitrary in its effect upon nonparticipant subjects when the interests of politicians making the consent decision diverge from the interests of the affected population, and when the researcher can offer inducements to the politicians to make a decision unrelated to their constituent interests. In Green Bay, for instance, it appears that the city council perceived a way to raise taxes without incurring the political costs to themselves, and weighed that personal interest above the interests of their constituents at risk.

If a surrogate consent provision should be added to the regulation, it should be specified that all of the elements of information which must be presented to a subject in order to gain individual informed consent must be presented in writing to the local or state official who executes the affidavit of surrogate consent. Although the procedure be different, and the giver of informed consent not the person affected, the substantive elements of consent should remain.

It seems clear that, absent addition of a waiver provision to Part 46, either it will be impossible to perform some social science research within the constraints of the regulation, or the modification clause will continue to be used as an invisible, unregulated, unarticulated waiver. Addition of a waiver would, assuming the latter prognosis, actually increase the protections available to nonparticipants at risk in social science research funded by DHEW.

Surrogate consent of some form will, assuming the availability of waiver or modification, maximize the protection available to non-participants with whom the researcher does not come into contact.

14/

12. Compensation of Subjects; Restoration of Status Quo Ante

The regulation is silent on whether, and under what circumstances, the researcher or the Department has the responsibility to compensate a subject. For example,

- (i) Should the Department sponsor, and should each research investigator be required to pay premiums into, a no-fault insurance system which will compensate subjects for unforeseen harm, the possibility of which was not mentioned to the subject by the investigator in the process of obtaining informed consent?
- (ii) If such a system is established, should subjects be compensated not only for unforeseen harm but also for improbable catastrophic harm, the possibility of which had been foreseen and explained by the investigator to the subject in the process of obtaining informed consent?
- (iii) Is there more of a duty to compensate catastrophically harmed nonparticipants from whom informed consent was never sought, in comparison to subjects who gave informed consent after having been warned of the small risk of foreseeable catastrophic harm? Assuming that the harm is not catastrophic, is there greater responsibility to compensate nonparticipants who never gave consent, in comparison to subjects?

What is the operational meaning of that greater duty toward nonparticipants who did not give consent, if such duty exists?

- (iv) After a social science experiment is over, does the research investigator have the responsibility to insure the status quo ante--to ensure that subjects are left after the experiment no worse off than they would have been had they never participated in it, or no worse off than they were when it began? Does the researcher have, for instance, the obligation to guarantee reinsurability for participants in a health insurance experiment who have allowed their pre-existing policy to lapse, or to ensure that subjects in a housing allowance experiment can obtain, if and when they are compelled to leave their experimentally subsidized housing at the end of an experiment, housing equivalent in quality and price to what they had before they began receiving the allowance?
- (v) Has the investigator a similar responsibility to restore the status quo ante for a subject who withdraws in the middle of a research project?
- (vi) Has the investigator a similar responsibility toward a non-subject in the experimental community who emerges harmed at an experiment's termination?

These, and other compensation issues, warrant amendments to Part 46 and consideration by the Commission.

Conclusion

Based upon the conceptual framework of a biomedical research model, the current regulation on protection of human subjects is inappropriate, in a number of major respects, to effective regulation of social science research. The response to the regulation, both by non-"H" agencies of the Department and by private research investigators, indicates that it is either not being applied to social science research at all or, where applied, has the potential of skewing substantially the data collected by that research.

The Commission ought closely to examine the current regulation in order to determine what amendments to it, if any, should be recommended in order to maximize the protection actually available to human subjects and to other persons at risk arising from social science research funded by the Department.

Footnotes

1. On risks arising from publication or policy application of research results, see also Alice M. Rivlin and P. Michael Timpane (editors), Ethical and Legal Issues of Social Experimentation, Washington, D. C.: The Brookings Institution, 1975 /hereinafter, "Brookings conference"/, pp. 73, 78, 81.
2. Ibid., p. 52.
3. Ibid., p. 78.
4. Ibid., p. 73
5. Ibid., p. 65
6. Ibid., p. 107.
7. Ibid., p. 114.
8. Ibid., pp. 69-70.
9. Lloyd B. Lueptow (Summarized by Keith Baker), Bias and Non-Reponse Resulting from Informed Consent Procedures in Survey Research on High School Seniors, unpublished, DHEW: Office of the Assistant Secretary for Planning and Evaluation, January 1976, pp. 43, 6.
10. Donald Campbell et al, Protection of the Rights and Interests of Human Subjects in Program Evaluation, Social Indicators, Social Experimentation, and Statistical Analyses Based Upon Administrative Records, Preliminary Sketch, January 1976, p. 13.
11. Brookings conference, pp. 77, 95, 110. 125, 171-72.
12. Ibid., p. 172.
13. Ibid., p. 110n4.
14. On compensation of subjects and on restoration of status quo ante, see ibid., pp. 11, 18, 54, 57, 63, 70, 76, 77, 103, 174.

IV

RISK/BENEFIT CRITERIA

SOME PERSPECTIVES ON THE ROLE OF ASSESSMENT OF RISK/BENEFIT
CRITERIA IN THE DETERMINATION OF THE APPROPRIATENESS
OF RESEARCH INVOLVING HUMAN SUBJECTS

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INTRODUCTION

The draft of a recently compiled Annotated Bibliography on the Protection of Human Subjects in Social Science Research (Washington, D.C.: Bureau of Social Science Research, 1975, mimeo.) speaks of "the scarcity of material which is explicitly concerned with the assessment of risk for subjects involved in social science research." This scarcity or lack has now, fortunately, been considerably corrected by Dr. Robert Levine's staff paper for the Commission, "The role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects," (mimeo., Oct. 27, 1975). Since Dr. Levine did not limit his discussion to biomedical research but referred to behavioral research as well, and since I find his analysis altogether excellent in its cogency, its detail, its comprehensiveness, and its examples, I can be most useful by directly orienting my paper to his. In the first part of my paper, as I take up some general issues in the assessment of the risk-benefit ratio in behavioral research, I will be trying to add to, refine, extend, set in perspective, and evaluate Dr. Levine's discussion. In the second part of my paper I will present some findings from a small study I have done of the actual experience during the last three years of the Columbia University Human Subjects Review Committee, the peer review committee responsible for all the non-medical research carried out by the Columbia faculty. I will also present a few other available data on actual experience in peer review groups with the risk-benefit issue. Finally, in the third and last part of my paper, I would like to say something about ongoing and needed research on the risk-benefit issue.

Too much of the discussion of the ethical problems of using human subjects in research proceeds in terms of ethical abstractions not clearly related to the empirical data they are supposed to clarify in order for us to make ethical decisions. I find the ethical abstractions of values not all that hard to come by; they are not esoteric; they are usually available even to informed common sense. But the facts to which they refer, those that make it possible to estimate the weight of the several ethical abstractions and to balance off these values one against another in the process of ethical decision, those are often not available in any systematic and reliable form, nor are they easy to collect. That is why we need so much research for all aspects of the Commission's deliberations. For example, there is no lack of ethical abstractions for the discussion of fetal research or psychosurgery, to take two issues on which the Commission is specifically charged with responsibility. What has been lacking are reliable data on which to base established ethical principles for these two areas. The Commission has now supported useful research in both of them. More research is also essential to the Commission for its deliberations on the ethics of behavioral research on human subjects.

SOME GENERAL ISSUES IN THE ASSESSMENT OF THE RISK-BENEFIT RATIO IN BEHAVIORAL RESEARCH

1. Is the assessment of the risk-benefit ratio in behavioral research fundamentally different from or similar to such assessment in biomedical research?

During the last few years, as behavioral researchers have become aware that their work was to be subject to ethical peer review in the same way as that of their biomedical colleagues, they have responded with much of the same uneasiness, hostility, and conservatism earlier displayed by these biomedical colleagues. (See Bernard Barber, "Liberalism Stops at the Laboratory Door," 1975, mimeo., and Barber, "Social Control of the Powerful Professions," 1975, mimeo.) As a part of their complaint against the imposition of ethical peer review on behavioral research by the D.H.E.W. regulations in 1971, they have said that their work should not be covered by "the medical model" that they allege is implicit in the D.H.E.W. regulations. Just how their work with human subjects, and just how the problems of ethical control in their area, are different from "the medical model," they do not make quite clear. Yet they are raising an important question. How different are the ethical problems of behavioral and biomedical research? Is the assessment of the risk-benefit ratio different in behavioral and biomedical research?

Perhaps just because Dr. Levine did not in his paper set himself the task of answering this question directly, indeed he did not take it as in any way his task, I find the answer that is implicit all the way through the paper all the more convincing. That answer, it seemed to me as I read and re-read Dr. Levine's paper, is that the similarities are far, far greater than the differences between biomedical and behavioral research in respect of the problem of assessing risk-benefit ratios. I found large and fundamental similarities with regard to such matters in Dr. Levine's discussion as: (a) the basic meanings of what are injuries, what are benefits; (b) the specification of the significant dimensions

of risks (likelihood, severity, duration, reversibility, early detection, ability to treat or correct) and benefits (Dr. Levine himself says, p.38, "The benefits may be analyzed similarly whether the research is in the biomedical or in the behavioral field."); (c) in his classification of categories of risks and benefits (physical, psychological, individual and social, legal, and economic); (d) in his list of some of the specific psychological harms that may occur from biomedical research (fear of rejection, guilt and self-blame, distrust); (e) in the nature of the task of assessment of the balance of risks and benefits; and, (f) in the question of where authority and control in the assessment process ought to exist. As is indicated in the sentence on p.38 of Dr. Levine's paper quoted above, occasionally even he makes the fact of similarity quite explicit. It is also clear from his frequent references to examples and consequences of behavioral research; the implicit assumption of these references is the similarity to biomedical research. This similarity is also manifest in "A Checklist of Ethical Issues in Social Experiments" prepared after a recent two-day Brookings Institution Conference on Ethical and Legal Issues of Social Experimentation, a Conference in which social and medical experiments were explicitly compared with one another. The Checklist's section on the question, "Have you specified and reviewed the benefits and harms of your experiment?" is no different from what such a section would look like for biomedical research. (Alice M. Rivlin and P. Michael Timpane, eds., Ethical and Legal Issues of Social Experimentation, Washington, D.C.: Brookings, 1975. See also, Henry W. Riecken and Robert F. Boruch, eds., Social Experimentation: A Method for Planning and Evaluating Social Intervention, New York: Academic Press, 1974, pp.246-8, 252-3.)

Fundamental similarity is not, of course, identity. While the principles and procedures of risk-benefit assessment in both fields are fundamentally the same, we should be alert to and responsible for such differences as also occur. But I think we get a better start on understanding risk-benefit assessment in behavioral research if we start with the fact of similarity and the useful immediate guide that gives us to good practice with respect to behavioral research. Indeed, there is no good evidence that peer review groups considering behavioral research protocols have not been able to operate with the standard D.H.E.W. regulations for all research. It seems to me that the burden of an argument for difference, whether it is a general argument or applies only to specific points, lies with those behavioral researchers who choose to assert it.

On one important matter of similarity or difference between behavioral and biomedical research, the relative overall amounts of riskiness or injury, on the one hand, and of benefits, on the other, I am not now committing myself. This is a more complex aspect of the problem of similarity and difference, hard to discuss in the absence of data, not to be left to mere opinion or prejudice. I will come back to this issue later after considering a little further what we mean by risk and injury.

My summary view, then, is that there is very large similarity and overlap in all fundamental aspects of the problem of assessment of risk-benefit ratios in biomedical and behavioral research. Some consequences follow from this similarity which it is useful to point out. One consequence is that despite the fact that research institutions often have different ethical peer review committees for behavioral and bio-

medical research because of the different technical substance involved in these two kinds of research, these different committees, because of the great similarity of their tasks, ought to have much more communication and cooperation with one another than they now do. Another consequence is that it would be very helpful all around to include more behavioral researchers in the process of establishing general principles and rules for ethical treatment of the human subjects of research. We all owe a great debt to N.I.H. and D.H.E.W., where this process has been chiefly located, but it has perhaps been too largely in the hands of biomedical researchers. Behavioral scientists would be especially valuable for their awareness and insistence on the necessity for research-based data and decisions in all aspects of the ethics of experimental research on human subjects.

2. The dimensions of "risk": amount and probability of injury.

Before proceeding further, it will be helpful to discuss a small but important definitional point made by Dr. Levine at the very beginning of his paper. He is quite right, I think, in feeling uncomfortable with the ambiguity in the meaning of the term "risk" as it is now used in a taken-for-granted way in all discourse on risk-benefit ratios. He is right that this now-standard usage actually implies two different elements, one the amount of injury or harm that may be done to research subjects, two the probability that the estimated amount will occur. If we make these two elements explicit, by calling one "amount of injury" and the other "probability," we gain a number of advantages. First, we make it explicit that we are talking about injury, a very concrete term and one that leads on quite directly to making very specific statements about the nature of that injury. Second, we see more easily that there can be a

varying relationship between injury and probability. Small injuries may be very probable and large injuries may be most improbable. Such various combinations are important for the decisions made by peer review groups. Indeed, the researcher may want to provide, and the peer review groups may want to require him to furnish, a set of possible injurious outcomes of research, consisting of different combinations of amount and likelihood of injury under different conditions. Anything we can do to be clear and specific will make our peer review group decisions easier and better. This new usage, in which amount of injury and its probability of occurrence are both specified so far as possible, would be equally applicable and equally valuable in both biomedical and behavioral research.

3. The "biological person" and the "social person".

We may clarify the underlying issues and see the fundamental similarity in the outcomes of biomedical and behavioral research a little more clearly still if we adopt for present purposes a somewhat different classification of the types of injuries ("risks") and benefits than the one Dr. Levine has taken over from common usage (physical, social, psychological, etc.) We may speak of injuries or benefits being done to or occurring to either the "biological person" or to the "social person". It has been the pattern in discussion of the ethics of the use of human subjects to say that there are two essential issues, "the risk-benefit ratio" issue and "informed voluntary consent" issue. The implication of this way of speaking is that the first issue, risks and benefits, concerns only the "biological person" and that the second issue, informed

consent, concerns the "social person". But we can now see from Dr. Levine's discussion and examples that the injuries and benefits of biomedical research, as much as of behavioral research, involve the "social person" as well as the "biological person". Biomedical research can injure the "social person" by causing him to feel guilt or anxiety or a sense of being discriminated against; it can injure the social body by creating distrust between physician-investigators and their patient-subjects or by discriminating in its selection of research subjects, as by using the poor disproportionately often, for all types of experiments and, even worse, disproportionately often for those experiments where the risk-benefit ratio is unfavorable. (For the data on these two patterns of discrimination, see Bernard Barber, John Lally, Julia Makarushka, and Daniel Sullivan, Research on Human Subjects, New York: Russell Sage, 1973.) For biomedical research, then, it is not just "informed consent" that applies to the "social person" but all aspects of that research.

Indeed, perhaps we can see this point more vividly by noting that to a considerable extent it is the social and cultural definitions of a society that determine what is to be considered an injury even to the "biological person". As we consider the difficult questions of what is to be considered an injury to the fetus or the terminally ill as "biological persons," we see how much the "biological person" is socially defined. Even for biomedical research, then, the "biological person" and the "social person" overlap and blend into one another.

For behavioral research, of course, the overlap and merging are clearer. For one thing, there is less possibility, obviously, of harm to the "biological person," though Dr. Levine gives some examples from psychiatry where this occurs. The primary concern in

behavioral research is with injury to the "social person". In this perspective, there is no difference for behavioral research between the "risk-benefit ratio" issue and the "informed consent" issue. All injuries on either ground tend to be to the "social person". Violations of informed consent regulations are as much injuries to the "social person" as are injuries to personal esteem or reputation. "Deception" in psychological experiments or in social research (through the use of "unobtrusive measures") are injuries even though a peer review group may mark them down as a violation of the rules of informed consent.

In sum, when we consider the degree of relativism in our definitions of the "biological person" and the "social person," when we see how they overlap and interact with one another, we are impressed with the great similarity of the possible injurious outcomes of biomedical and behavioral research. In making ethical decisions about the use of human subjects in any kind of research, ultimately what we are interested in is the moral status of the "social person".

4. The fact and necessity of risk-benefit assessment.

Absolutistic and perfectionist thinking about risk benefit assessment procedures, which occurs among some biomedical and behavioral researchers, and not least of all among those of them who are opposed to such procedures, is the great enemy of realistic and continuing attempts to achieve improvement in these matters. We should be impatient with absolutistic and perfectionist thinking which expresses itself in such declarations as, "You can't truly get informed consent," or "You can't really make a risk-benefit ratio assessment". Realistic

thinking on risk-benefit ratio assessments, whether in biomedical or behavioral research, proceeds on the premise that a considerable amount of such assessment will in fact be easy, another and smaller amount may be difficult but still possible, and that only a very small amount will be so difficult as to be considered "impossible". The practical and moral necessity for such assessment is obviously there, and the fact of relatively successful performance is also clear. Just as we make rough but approximately satisfactory risk-benefit assessments in the thousand-and-one routine and extraordinary activities of daily life, so we now have a considerable experience with the fact that biomedical and behavioral research peer review groups are making risk-benefit assessments on the same terms and in a routine way. For the majority of such assessments, the easy ones, there is no great moral or cognitive strain on the peer assessors. But for the more difficult ones, as we learned by mail questionnaire and personal interview from the six hundred or so biomedical researchers who participated in our two studies and made such risk-benefit assessments for us of "hypothetical but real" research protocols, there is some strain. (See Barber, et al., op. cit.) Nonetheless, in a sufficient number of cases, not only among our study respondents, but in actual peer review groups, scientific peers do overcome this strain and make conclusive assessments.

We should remember that, even where difficulty and strain occur in the assessment process, they are worthwhile just because the process of making assessments has value over and beyond the outcome or product of the process. Whether routine or difficult and causing strain, the

process of explicitly estimating injuries (amount and probability) and benefits (again, amount and probability) is important in itself. The process is in itself "consciousness-raising;" it leads to higher ethical awareness. One hopes that the product, now or eventually, will also be better, but that happy condition we should not expect ourselves to guarantee. We should not expect, and certainly not require perfection of risk-benefit assessment in all cases from our biomedical or behavioral review groups. Perfection in all cases is for utopias and heavenly worlds. Moreover, we should inform the general public that we do not guarantee perfection of assessment product but only excellence in the process. We should inform them that we are prepared to defend scientific research assessment, when it is conscientiously and competently carried out by professional peer review groups, against all demands for utopian perfection of product.

Another way in which unrealistic expectations for risk-benefit assessment products express themselves is in the call for quantitative and complexly mathematical formulations and specifications of the risk-benefit balance in any particular piece of biomedical or behavioral research. I do not think that the use of the terms "outweigh" and "sum" in the D.H.E.W. regulations about the risk-benefit ratio is intended to be anything more than metaphorical. In everyday language, certainly, we use such terms in full understanding of their metaphorical character. The D.H.E.W. regulations enjoin the peer review groups only to be prudential, to do the best they can as they think about "balances," "sums," and "weights". We have too much the fearful tendency to think that D.H.E.W. is expecting more of us than we can produce, that we must search for hidden meanings and covert

expectations in its necessarily vague and metaphorical language. There are, of course, those who have developed elaborate and formal mathematical equations for a variety of social processes, systems, and "cost-benefit" ratios; they would love to have peer review groups try out their exercises. But I think Dr. Levine is correct when he says (p. 48) that "At this point it seems appropriate to avoid using mathematical models to calculate risk-benefit ratios...". Rougher and simpler modes of "measurement," what the sociologist Paul F. Lazarsfeld has called "qualitative measurement," is more than adequate for a satisfactory ethical process right now in making risk-benefit assessments. Wherever more quantitative measurement or even mathematical modeling are possible, of course, they should be encouraged, as in some epidemiological studies of injuries and benefits from biomedical or behavioral research. But most risk-benefit assessment processes cannot be fully quantitative just yet.

On another aspect of these assessment processes, on the answer (pp. 53ff.) Dr. Levine has given in his memorandum to his question, "Who has the authority or responsibility to assess risk-benefit criteria in the determination of the appropriateness of research?" I should like to make some comments. I agree with Dr. Levine that a "central role" should be assigned to the IRBs, though, as I have argued elsewhere (Barber, et al., op. cit., Ch. 11), it is important that IRBs should include lay outsiders in all cases and, in some, also medical specialist outsiders from other research institutions. I further agree with Dr. Levine that the subjects themselves have an important part to play in prudential assessment processes. Finally, I think he has well described the role that national review boards could

play in especially difficult assessment decisions and also in improving and making easier the work of the local committees.

Nevertheless, because the social interaction processes involved both in risk-benefit ratio assessments and in informed consent procedures are quite complex, include a number of different significant social actors and an extended time period not covered by the authority and control mechanisms Dr. Levine has discussed, I would like to see other authority and social control mechanisms included. The ethical education of the physician, either in medical school or thereafter, is not yet satisfactory. A more satisfactory education ought to be an important additional support for satisfactory and authoritative risk-benefit assessments. So too ought strengthened and more self-conscious informal peer control mechanisms, such as informal conversations, consultations, advice and even interventions. Finally, I would like to see some better education for potential research subjects, who are all of us, in both their rights and obligations as research subjects. Here, as in other social realms, there is probably a useful role for a variety of responsible "consumer" protection agencies, especially with regard to the protection of the particularly vulnerable social categories such as children, prisoners, and the mentally ill, where their own resources are not sufficient to participate prudentially in the process of being research subjects. Certainly, for the improvement of risk-benefit assessment processes we need to pay a good deal of attention to who is involved in those processes, and how, that is, what knowledge of and control over the processes they actually have. Research on these matters will be valuable.

5. Is behavioral research less injurious than biomedical research?

One way of summing up our comparative perspective on risk-benefit assessment in biomedical and behavioral research is to ask ourselves, Is behavioral research less injurious than biomedical research? That is, overall is there a better risk-benefit balance for biomedical than for behavioral research? The quick and all-too-current answer, of course, is yes. Since biomedical research is more often than behavioral research a life-and-death matter, both causing grievous injury sometimes but more often bringing life itself, it is on the whole productive of a better risk-benefit ratio.

And yet, before we think there is a great dissimilarity, we need to look at a few qualifying facts. First, it is important to remember that there is very little life-and-death research even in biomedicine. The study my colleagues and I did of some 300 biomedical researchers using human subjects and who reported to us about 424 different research projects in which they were involved showed that most research is both scientifically and ethically trivial, far from being a life-and-death matter. Taking note of this fact, and remembering also that we do not have even a rough calculation of the total amount of harm and good that either biomedical or social research has given us, we may well express a little hesitation about making firm and precise comparisons of the two. Finally, we have to remember that many people consider some social injuries and benefits even more important than biological health and life itself. Orwellian 1984-ish nightmares about social slavery and total thought control can seem more real and more horrible to people than harm, or even

death, done to the "biological person". Insofar as it is consequential for such fundamental injuries and benefits, behavioral research is obviously of great importance to us. The assessment of its risk-benefit ratios is not a small or indifferent matter.

In sum, while we may agree that, overall, probably more hangs in the balance from biomedical research, still a great deal of the greatest importance is involved in the injuries and benefits of behavioral research. The assessment of the balances of these injuries and benefits is of the first importance for the ethics of scientific research using human subjects. If it is not the most important problem we have in this field, neither can it by any moral or prudential standard be called unimportant.

SOME EMPIRICAL DATA ON RISK-BENEFIT ASSESSMENT IN BEHAVIORAL RESEARCH

I have been arguing for the fundamental similarity, in principles and procedures, of risk-benefit assessment in biomedical and behavioral research. Arguments, of course, and especially one so important for policy as this one, should be supported by facts, and preferably systematically collected and reliable facts. What are the facts regarding actual processes of risk-benefit assessment in biomedical and behavioral research?

Unfortunately, but just as is the case in nearly all areas of the ethics of research using human subjects, good data are hard to find. What we have instead are mostly scattered, unsystematic statements, as well as a few more systematic facts, not so much because they prove the case for or against the argument of fundamental similarity, but simply as a basis and a background for the better data

that ought to be built on them.

For eventual comparative purposes, though the data for precise comparison from behavioral research are not now available, we may start with some data on risk-benefit assessments in biomedical research. First, as to amount of risk (probability of risk occurring was not asked): When we asked some 300 biomedical researchers at University Hospital and Research Center to estimate the amount of risk involved in 422 different studies they were doing on human subjects, they said that 1% (4 studies) involved "high risk," 2% involved "moderate" risk, 8% involved "some" risk, 45% involved "very little" risk, and 44% involved "no risk at all". (Barber, et al., op. cit., pp. 39,45.) Second, when we asked these researchers also to estimate amount of benefit for subjects, and amount of possible benefit for future patients, we were able to establish risk-benefit ratios. We discovered that in 18% of the studies, risk outweighed benefit to subjects; these we called the "less favorable" studies. We also discovered that some of these 18%, amounting to 8% of the total of 422 studies, were what we called the "least favorable" studies because the risk-benefit ratio was unfavorable even when we added benefit to future subjects to benefit to present subjects. (Ibid., pp. 47,50)

For present comparison with these data, all we have is some unsystematic data from three institutions, University of California, San Diego; University of California, Berkeley; and Columbia University. The San Diego data were presented by Professor George Mandler at a recent symposium on the ethics of research on human subjects at an annual meeting of the American Psychological Association. (Behavior Today, Sept. 29, 1975, 573-574.) Mandler reports that his university

has separate committees for behavioral and biomedical research; this practice is followed by many major universities, though we do not know how many. He further reports that at San Diego, whereas "about 90% of the research projects generated by the medical school involve some risk," only 25% of the research submitted to the behavioral peer review group involves some risk. It should be noted that the 90% "some risk" figure for the San Diego biomedical group compares with a figure of 56% in the university hospital and research center studied by me and my colleagues.

In his "DHEW Regulations Governing the Protection of Human Subjects and Non-DHEW Research: A Berkeley View," (mimeo., 1975) Professor Herbert P. Phillips, the Chairman of the Committee for Protection of Human Subjects, a committee which covers only behavioral research, reports that "the vast number of projects currently examined by the CPHS involve 'no risk' or extremely low risk to the human subjects". What does "vast number" mean? Professor Phillips continues: "Under the present review system, no more than 10-15 out of every 100 cases that we examine require a modification of research design to better protect the human subjects; and in the vast majority of these 10-15 cases the 'risks' to the subjects are so self-evident that the cases would have to come to the CPHS's attention, whatever the system of review." Professor Phillips concludes with a statement that is representative of the views of those behavioral researchers who would like to alter the present procedures of risk-benefit assessment for their field: "It just does not seem reasonable to have 85-90% of Berkeley researchers, and members

of the CPHS, waste so much of their valuable time and energy on lengthy, but essentially meaningless expositions proving that no harm will come to their subjects, or, conversely, that they are morally upstanding scholars. There is an element in this process that is clearly reminiscent of the California 'Loyalty Oath'".

Being very much aware of the lack of empirical studies of risk-benefit assessment in behavioral research, when I was asked by the Commission to prepare the present paper I decided to do a small study on the experience in this field of Human Subjects Review Committee at Columbia University. I have been a member of this Committee for the past three years and am now its Chairman. It is on this experience that I am reporting. Unfortunately, we do not ask our member-reviewers to do more than indicate whether there is "some risk" or "no risk," so my data are not finely graded either as to amount or probability of risks.

I should also report that I set down my pre-research impressions as to what my findings might be. The fact that these impressions proved wrong turned out to be instructive. My pre-research impression was that there would be relatively few expressions of concern about harm or injury from our reviewers; I felt that informed consent would be the primary issue of concern. The data showed me wrong and I realized that I had been thinking of injury as only to the "biological person". When injury of various kinds to the "social person" is assessed, then the risk-benefit issue turned out to have been of greater importance to the members of our Committee than informed consent shortcomings. It was this finding that led me to see the usefulness of the distinction between the "social" and the "biological" persons that I have presented

at the beginning of this paper.

What are my actual findings? During the period from September, 1972, to August, 1975, the Columbia University Human Subjects Review Committee screened 90 behavioral research proposals that passed through the University's Office of Projects and Grants. The members of the Committee include Community members, university research staff, and faculty members from anthropology, law, business school, social work, sociology, and psychology. Since it is our procedure to have three members review each proposal, there should have been 270 reviews for the 90 proposals. We could find only 249 in the files and we report on these. Of these 249, just about half, 123 (49%) were unqualified approvals with regard to both issues, risk-benefit and informed consent. 48 of the reviews (19%) raised questions about informed consent. 79 of them (32%) had questions about what we called "risk". and 49 (19%) had questions about what we called "confidentiality". (It should be noted that questions by reviewers, where there were any, could add up to more than 50% because a reviewer could mention both issues in the same review.) Thus, one in three of the individual reviews raised explicit questions about what our standard check-list calls "risk". But though an additional 49 (19%) of the mentions were about what the check-list calls "confidentiality," it is clear from the comments of the reviewers who mentioned this that they were thinking of injury to the "social person" just as much as when they mentioned "risk". For them, violations of confidentiality were just as much injuries as is the "risk" of damaging the individual's self-esteem or his social reputation. "Risk" factors seem to be those that directly cause such harm as embarrassment

or loss of reputation. "Confidentiality" still involves potential injuries though the harm it causes in the form of embarrassment is indirect, a result of making the individual's identity visible and thereby exposing him to harm. Altogether, then, injury to the "social person" is thought by our reviewers to occur more often than just the explicit mentions of "risk" would suggest. These data from the H.S.R.C. experience indicate that some amount of risk is a not infrequent occurrence in behavioral research.

What are some of the injuries our reviewers mentioned? The list contains no surprises: embarrassment, loss of privacy, disclosure of confidential information, danger of arrest, adverse effects on family or larger social network relationships, anxiety, fear, self-incrimination, and harmful new self-awareness. Each of these general categories includes a number of different specific cases; it is the useful function of the Committee reviewers to discern the general harm in the variety of specific concrete cases. It would probably be a helpful guide to researchers if a list of such general categories of potential harm could be published, including several recurrent and representative cases for each category.

SOME CURRENT AND NEEDED RESEARCH

I should like to end this paper as I began it, with an emphasis on the need for more and better research on the problem of risk-benefit assessment in behavioral research. Such research should be explicitly comparative with research on biomedical risk-benefit assessment. It should also be systematic and cumulative, with each piece of work building and improving on research that has gone before. Research

should test all our assumptions and seek to make the process of risk-benefit assessment both more effective and more efficient. For we want assessment principles and procedures that will do their job well and will be least costly of researchers' and other participants' time.

Fortunately, we have a few studies underway that will add to our knowledge and serve as valuable models beyond the very few that now exist. One of these current studies is the Commission's own study of IRB's. The other is the N.I.M.H. funded study by Drs. Glen D. Mellinger and Mitchell Balter, "Public Judgments Regarding Ethical Issues in Research."

We should remember that the improper use of human subjects in research has only recently become widely defined as a social problem. The task of ameliorating this social problem is not simple and is bound to take time. Effective remedies will require no small amount of social change in several social circles. Expert, and expensive, social research of the kind represented by the Commission's study of IRB's and the Mellinger-Balter study of public views has an essential part to play in making this social change possible.

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THE ROLE OF RISK/BENEFIT ANALYSIS IN THE CONDUCT
OF PSYCHOLOGICAL RESEARCH

Gregory Kimble, Ph.D.

The Role of Risk/Benefit Analysis in the
Conduct of Psychological Research

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Concern about the ethics of psychological research is a fairly recent development and the reasons for the development of this concern are of some interest. As long as the psychological investigator confined himself to rats learning mazes, to college students mastering lists of nonsense syllables, to his own colleagues' psychophysical judgments of stimulus intensities in the interest of constructing scales of sensory magnitudes and to studies of eyelid conditioning aimed at uncovering the basic "laws" for a behavior system there were no serious problems. About the most serious moral accusation anyone could make about such research was that it was pretty much of a bore for the subjects who participated. It was when the science began to study obedience to authority, racial differences in cognitive abilities, the behavior of homosexuals in public places, the decision-making activities of the members of juries and the personal characteristics of people hired for and fired from governmental positions that serious questions began to arise. The general point to draw from this comparison is that the more important the topic of investigation, the more sensitive are the ethical issues it raises. Research on the more recent topics invades the privacy of the individual in important ways. In some cases disclosure of the information obtained might put the person in danger of losing his reputation or of being arrested and jailed.

Looking to the future it is clear that we will have to continue to face these ethical issues for two reasons, first psychology has developed

methods that allow the effective investigation of important social and personal issues and second the situation in the world demands such investigation whatever the consequences produced directly by research.

As my grandmother would have put it, "The world is going to Hell in a handbasket," or as the more polite would say "The quality of life is deteriorating." The earth is overpopulated and there are places where people starve to death. Our supply of fossil fuel is about exhausted. Alternative sources of energy are not being developed rapidly enough and people have not changed their behavior in ways that would conserve what we have. The concern of people for the welfare of each other has reached a new low, the well documented refusals of people to come to the aid of others in trouble being the obvious reference on this point. In last night's paper there was the story about a gang of teenage hoodlums who boarded a bus in San Francisco, beat up and robbed passengers and tried to repeat the performance on another bus before the police stopped (but did not arrest) them. Over fifteen percent of the population have failed to develop the intellectual skills required to deal effectively with a newspaper ad for groceries. The list could go on: "pollution," "divorce," "child abuse," "the alienation of youth," "the frustrations of middle life" and "the indignity of old age" suggest just some of the problems that could be presented in more detail but that is not my purpose here.

My immediate purpose is to direct your attention to the fact that most of the problems I have hinted at above are psychological problems. Physical technology will not provide the required solutions which must come from knowledge about behavior. Unfortunately the knowledge does not exist and only research will provide it. Research, however, puts the

research participant at risk. This last point poses the question to be discussed: Are these risks appropriate given the benefits research provides?

Risk/Benefit Analysis

Consider, to make the point concretely, the research of M. M. Berkun and his colleagues (1962) on stress in simulated wartime situations. In one experimental condition a group of army recruits were passengers aboard an apparently stricken plane that had to crash land. In other conditions recruits were subjected to a reported threat of accidental nuclear radiation, to the telephoned information that a forest fire had surrounded their outpost, and to a fictitious report that they were being subjected to artillery fire by members of their own army. In all of these situations the realism of the crisis was enhanced by the use of noise, darkness, rugged terrain, smoke or whatever was required. In each of these situations the recruits' radio transmitters, the most likely instrument for securing help, "failed" and the behavior of interest was the recruits' effectiveness in trying to repair it. Under the stress of the situation some of the men left in cowardly retreat and many showed other signs of severe distress. Was it all worth it?

The standard answer to this question these days takes the form of a "risk/benefit" analysis. The risks born by the subjects in the experiment (the experience of terror, being deceived, living with the knowledge of cowardly behavior) are to be weighted against the benefits provided by the study (development of psychological screening measures, better knowledge about the effects of stress, possibly a more effective army). If the aggregate of benefits outweighs the risks the experimental procedure is justified; otherwise it is not.

In the rest of this essay I shall subject the risk/benefit analysis to its own analysis. I shall show, I think, two things: (1) that in any respectable mathematical sense of the concept risk/benefit analysis is a practical impossibility in this context but (2) that it brings certain considerations into focus in ways that contribute to the decision as to whether a particular piece of research deserves to be carried out.

The Dimensions of Complexity

In the abstract the idea of subjecting research plans to a risk/benefit analysis is very attractive. What would be involved would be the development of the ratio: aggregate of all the benefits/aggregate of all the risks. Ratios greater than 1.0 would allow research to proceed. Ratios less than 1.0 would put a stop to it. In practice, however, the situation is a bit like that of Alice in Wonderland after she had eaten the cake that made her shrink:

"The first thing I've got to do," said Alice to herself, as she wandered about in the wood, "is to grow to my right size again; and the second thing is to find my way into that lovely garden. I think that will be the best plan."

It sounded like an excellent plan, no doubt, and very neatly and simply arranged: the only difficulty was that she had no idea how to set about it.... (Carroll, 1946)

With risk/benefit analysis things are similar. The plan is excellent--very neatly and simply arranged--but faced with the problem of carrying the plan out it seems unlikely that anyone has any idea of how to set about it. I turn now to some of the reasons for this state of affairs.

Number of Variables

One of the most obvious points to make is that even for a single piece of research the number of risks and benefits that have to be considered is enormous. In his extensive review of this topic Levine (1975) breaks risks and benefits down into categories that apply to individuals and categories that apply to groups. Then he proceeds to identify several more specific items in each grouping. They include physical, social, legal and economic risks and benefits. Since each of these can be further broken down into many specific types of risk and benefit the list quickly becomes so long that it seems unlikely that a manageable risk/benefit equation could be constructed from these terms.

Subjectivity of Risks and Benefits

There is also another point to make: the significance of the components of the equation involve matters where there must be great individual differences and great differences among various social groups. In this connection, consider what must be the most controversial psychological research from an ethical point of view, that of Milgram (e.g. 1965). As most readers of this essay will know Milgram demonstrated that a good many Americans, prodded by nothing more than firm direction to do so, will administer a dangerously strong electric shock to a fellow human being just for failing to produce the right answers in a faked study of paired-associate learning.

The ethical question raised by this research involves the consequences for a subject of discovering this unpleasant truth about himself. For most people the effect would probably be ego-destructive. The extent of this reaction would vary for different people and for members of different social

groups (Smart and Smart, 1965). The assessment of risks, for this reason, would require (sometimes unattainable) information about the reactions of different individuals and groups to the same treatment. As we shall see later obtaining such information raises ethical questions of its own. For the moment it is important only to note that the subjective nature of risks and benefits adds to the problem of putting them into any realistic ratio form.

The Problem of Aggregation

Even if a catalogue of all the possible risks and benefits of psychological research existed, this information would only set the stage for further problems of great difficulty. It is possible to find references in the literature in this area which suggest that it is the "sum of" the risks and benefits that are to enter the risk/benefit ratio (Levine, 1975, page 45 ff.). Although it seems improbable that the various risks and benefits combine according to the rules of simple addition, it is unclear as to how they do combine or that the rules of combination would be the same for all conceivable ways of looking at a risk/benefit ratio. Such unclarity comes about largely because of the nonexistence of an appropriate metric for the quantification of risks and benefits.

Quantification of Risks and Benefits

Risks and benefits appear to have three properties that might enter into the process of assigning quantitative values to them. Both terms vary in a) probability of occurrence, b) the magnitude of the effect (positive value of the benefit and seriousness of what is risked) and c) the number of people affected. I shall concentrate on the first two of these quantities. As the discussion develops it will become clear

that these alone raise so many problems that it will not be profitable to say much about the third.

Risks. Confining ourselves to the major risk of subjects in the Milgram experiment in order to have a concrete example, we might note that each subject began participation with some probability of finding out an unpleasant truth about himself and this unpleasant truth would be in some measure destructive to the individual's self-esteem. But what values shall we place on these two aspects of risk?

We know that the actual probability that this subject would deliver the very strongest shock to the second individual in the experiment was about .60. Perhaps this should be the probability value. This quantity was one of the results of the investigation, however, and could not have served in a calculation designed to decide whether or not the experiment should have been done. Perhaps this probability of .60 could have been estimated--say by college students who have considerable experience as subjects or by psychiatrists who have professional knowledge of human reactions. Other research tells us that this would not have produced realistic estimates, however. When the experiment was described to groups of college students and psychiatrists the students estimated that 3% of the subjects would administer the strongest shock; the psychiatrists estimate was only 1%. Both were very far short of the actual probability. Obviously prior to the Milgram experiment this aspect of risk could not have been evaluated.

Without developing the argument in much detail the same conclusion seems to apply to the estimate of the seriousness of the self-revelation experienced by many subjects in this experiment. Without actually participating in the study the subjects could not know how they would react

or how they would react to their own reactions

Benefits. If anything, the points just made about risks apply with greater force to benefits but for a rather different set of reasons. Although subjects may benefit slightly from their participation in research--for example, by learning a little about research and knowing that they have contributed to an important enterprise--the eventual benefits usually go to others than those who actually participate in an investigation. The risks on the other hand are here and now.

As a brief aside it may be worth noting that for some people this state of affairs raises the question of whether it is right for some to take risks now when the benefits go to others later. The answer to this question appears to be that we benefit now from the contributions of those who served earlier and that the bargain is not so unfair as the question may make it seem to be.

Returning to the matter of quantifying benefits, there are several considerations that lead me to believe that it is unreasonable to expect any more success here than in the case of risks.

1. Applications of much research cannot be anticipated. This point has been made many times but I might add one item from my own research history. In an old study (Kimble, 1955) of shock intensity and avoidance learning, I did a preliminary experiment in which I showed that rats responded in two quite different ways to relatively weak and relatively strong electric shocks. The purpose of this pilot work was just to establish ranges of intensities to use in the main experiment on the effect of various intensities. As it turned out, however, the preliminary experiment had important practical applications. The two reactions were

affected differently by drugs and this fact made important contributions to the study of psychopharmacology.

2. The effects of research are cumulative. Whereas risks tend to be localized in time and centered on particular individuals, benefits are diffuse and may have their effects more through a change in attitude and atmosphere than through a direct influence upon any single aspect of the world.

I might cite, as an example of what I have in mind here, all of the work done since 1898 or so by the Thorndikeans, Skinnerians, and Hullians on the law of effect. Although I doubt that any single one of these thousands of studies ever was the basis for any significant educational innovation, the cumulative impact of the tradition was important. The current emphasis on reward for accomplishment rather than punishment for failure and the stress on student interest and motivation seems a direct consequence of the major ideas in the law of effect tradition.

3. How does one identify a benefit? The previous example will already have suggested to some of my readers that the neat (if implicit) categorization of the consequences of research as beneficial or the opposite is far too simple. Surely there are those who believe that the catering to student interest and the neglect of punishment in the schools mentioned above is to blame for the deteriorating cognitive competence of our population. Equally surely there are others who would point to exactly the same conditions as being responsible for the fact that American Scholars are the most productive in the world. If one argument is right and the other wrong the question of benefit hinges on which side is correct. If both arguments are correct, (which is possible if the effect of

reinforcement interacts with certain aspects of individual difference) the risk/benefit waters become very muddled indeed.

It is also important in this connection to make a related point. The knowledge generated by research is morally neutral. I does not know or care whether it is used for human benefit or harm. It may in fact benefit some people and harm others simultaneously. To illustrate, suppose that research on persuasive communication tells a candidate for political office how to run his campaign so as to win. In that case the product of research has benefited the winning candidate and harmed the loser.

A very similar conclusion arises from considerations relating to what happens to a single participant in an experiment. Referring to Milgram's work once more, suppose that a subject in such an investigation finds out that he is capable of inflicting cruel and possibly fatal punishment upon another person under the slightest of provocation. Is this a benefit or not? It could be a benefit one might argue, because it is better to know such things about oneself in order better to control such tendencies. But with equal force it could be argued that such knowledge is the opposite of a benefit because of the damage it does to self esteem and the possible negative effects on ones life later. Obviously the assessment of benefits is a much more complicated issue than first impressions may suggest.

A Temporal Consideration

Although I have certain objections to the model it is possible to draw an analogy between risk/benefit analysis and multiple approach-avoidance conflict situations. If one does draw the parallel another complication feature enters the picture. The values of the conflicting

components of a conflict change in time. It seems certain that the same thing must happen with risks and benefits.

To illustrate: suppose someone signs up to participate in an experiment next week. The chief negative aspect (risk) in the experiment is that it will involve electric shock, perhaps so strong that the participant will not be able to tolerate it. The chief attraction (benefit) is that the subject will receive \$50.00 for his participation. Since the subject does sign up obviously benefits outweigh risks--but that is a week before the experiment.

During the week things change. If conflict theory provides a guide both the subject's fear of the painful shock and his desire for the \$50.00 increase as the moment of participating in the experiment approaches. The fear increases faster than the desire for money and possibly to a higher level. It may lead the subject to drop out of the experiment just before the appointed hour.

What actually happens is not so important for our purposes as the fact that fear increases according to a steeper function than monetary desire. This means that a risk/benefit calculation involving these elements will have different values which depend upon the point in time where the calculation occurs.

Conclusion

My own conclusion, having developed all of these points, is that the plan actually to calculate a risk/benefit ratio as an aid to making decisions about the value of a particular piece of research is unrealistic. There are too many variables to consider. No quantitative indices of either risks or benefits exist and none seems likely to be developed soon. The

operational bases for constructing such scales are difficult to specify. About all that one can say is that the scales should probably be based upon the values of individual subjects. Finally even if the basic measures were available there is reason to suppose that ratios based upon them would change in complicated ways in time. To repeat, the formal use of risk/benefit ratios for the purposes of making ethical decisions about research seems difficult or impossible.

The Ethics of the Ratio Itself

Suppose we decide that the evaluation of research plans with the aid of risk/benefit ratios is not impossible but only very difficult. What then? At least one "then" appears to be that we have raised some issues that are partly logical and partly ethical.

Much of what I have covered in the foregoing pages of this essay makes the critical point. Largely the risks, but not most of the benefits, of research are born by individual people. For this reason I suppose that most of us would agree that the assessment of risks should be heavily weighted (if not totally determined) by those risks as they are perceived by the individual.

To illustrate what this means and where the argument leads let us consider the Milgram type of experiment for one last time. Suppose we are trying to recruit a particular subject for experiment and want to make a calculation of risks for him. For perfectly obvious reasons we cannot inform him of the fact that he will probably be led to treat another human being in a way that will make him feel guilty and ashamed of himself for a long time. Even if we could the subject would want to know more than the fact that the odds are 60/40 that he will obey and if he does

obey that he will be conscience stricken as a result. He would (or should) want to ask what the odds are specifically for him and how guilty he will feel.

Fortunately or otherwise, psychology does not have the ability now to answer such questions. But sometime it probably will and consider what that implies. It would mean that if we had the necessary information about this person's early upbringing, habits of cruelty, ways of experiencing guilt, relationships to authority and God knows what else we would be able to answer the questions raised specifically for him. But note that along the way we have invaded the privacy of the individual's personal life and that some of the information might, if disclosed affect his reputation or even put him in jail. In short the effective assessment of risks and benefits for any purpose seems certain to increase the risks.

Such considerations add a new dimension to the issue under examination. Most of this paper has been devoted to making the point that risk/benefit analysis probably cannot be carried out for practical reasons. This brief section has made the further point that perhaps it should not be carried out for ethical reasons.

Implications

So where does all of this leave us? If the formal application of the risk/benefit calculus to the planning of research is practically impossible and morally objectionable, what alternative are available? In my opinion there are no alternatives. Some form of risk/benefit thinking is the only reasonable way of looking at the problem. In the concluding pages of this essay I shall argue for the application of a redefined and less formal risk/benefit equation as an aid to decision making in the conduct

of research with human beings.

A General Position

The redefined risk/benefit ratio I wish to propose looks like this:

$$\frac{\text{Amount of Knowledge to Come from Research}}{\text{Risks as Seen by Reasonable People}}$$

I turn now to a discussion of the components of this proposed equation.

Knowledge as the benefit of research. It is clear of course that it is not the process of research itself that is potentially beneficial to mankind. Rather it is the product of research--the advances in knowledge to which it leads. This obvious point raises several questions that deserve comment.

Is it important to distinguish between the potential benefits of applied and basic research? In my opinion the answer to this question is "no," at least for the foreseeable future in the behavioral sciences. The point I have in mind here is that our knowledge in the behavioral sciences is so limited that it will be important to carry out basic research, applied research and research that attempts to bridge the gap between the two.

It is probably well understood that it would be a mistake in any science to restrict research strictly to applied problems. The trouble with such limited programs is that they are apt to produce results of limited usefulness. Typically the data obtained in applied research bear on some very specific problem and fail to generalize to other specific problems. A part of the aim of basic research is to obtain more general knowledge. Beyond that, as was mentioned earlier, the benefits of research are less predictable than one might hope and seem about as likely to come from basic research as any other kind.

On the other hand, at least in psychology, the time has come to make the heretical point that basic research carried out in the absence of any concern for applicability has its own failings. The history of research on the psychology of learning from roughly 1929 (Hull's Functional Interpretation of the Conditioned Reflex) to roughly 1952 (Hull's A Behavior System) will serve to make the point. In my personal estimation research carried out in this period was probably more "scientific" than research that is being done now. The trouble with it, however, was that the areas of investigation (the non-threatening topics mentioned in the first paragraph of this essay) appear to exist only within the artificial confines of the laboratory. It was when the psychologist of learning turned to more realistic lines of investigation (free recall, lapses of memory exemplified by the "tip-of-the-tongue" phenomenon, memory for the content of paragraphs) that more useful advances began to occur. This point now seems well on the way to receiving general acceptance in experimental psychology. The former disdain for application has now nearly been replaced by a concern for the "ecological validity" of experiments.

Research quality and ethical behavior. The proposal that the numerator of the revised risk/benefit equation should be "amount of knowledge to come from research" has an interesting implication: If the equation provides an index of ethical research behavior (as I intend that it should) the conduct of bad research is unethical. This is because research that is poorly conceived, improperly executed or inadequately analyzed will add nothing to knowledge and might even contribute a negative increment. Under such circumstances even the most trivial risks to subjects are

unwarranted.¹

¹I owe an expression of appreciation to Verna Shmavonian who started me thinking about how the quality of research enters the ethical picture. She is in no way responsible, however, for the curious twist this thinking finally took.

Risks as seen by reasonable people. As with the case of benefits we can begin this discussion with an obvious point. It is unreasonable to ask for a complete accounting of risks prior to deciding to conduct a particular bit of research. The risks are too numerous and impossible to predict. Moreover, (since the only sensible way to look at these risks is in terms of what they mean for individual subjects) assessing the risks would sometimes pose greater ethical questions than the research itself. This last statement identifies my reason for leaving the assessment of risks up to the judgment of "reasonable people."

But who are these reasonable people? I think there are three classes of them--the investigators themselves, subjects and institutional review groups. Beyond that it seems to me that in the great majority of the cases investigators will be the individuals in the best position to identify the risks. This is not just a self-serving evasion of the issue and I wish to push the point somewhat vigorously.

The ethics of investigators. Why is it important for me to write this essay? I think because the times require it. The methods and motives of those who do research with human subjects are not very well understood by the general public. This is part of a generally anti-intellectual climate that places a low value on knowledge, scholarship and research. In such a climate it is not surprising to find that a cloud of suspicion

surrounds research with human beings. Either the investigator is seen as an irresponsible player of trivial games or else he is cast in the role of the bad guy--a behavioral voyeur whose aims at best are to expose the most scandalous aspects of the human condition. Under such assumptions is it not reasonable to demand a complete ethical accounting of those involved in research?

Although I have no intention to minimize the importance of the ethical issues I do think that it is essential to attempt to restore perspective and I have two general points to make. The first is that the devaluation of scholarship is a serious threat to our survival even as a species. More of that later. The second has to do with the ethical values of investigators.

Put bluntly, I suspect that these values tend to be considerably higher than those of a good many people with whom subjects have daily contact--for example the used car salesman, the TV repairman and the precinct politician. Moreover the research scientist is sensitive to the ethical issues. Long before the current spate of codes of research ethics began to appear on the scene, similar codes had been developed in the behavioral sciences. By reason of a history of concern for the welfare of his subjects, the research investigator is, I think, in a better position than almost anyone to make the ethical decisions.

Without going into great detail on any point the following list of ethical principles taken from the code of the American Psychological Association (Cook et al., 1973) illustrates the range of considerations which the ethical investigator takes into account in his assessment of risks.

- The investigator is personally responsible for the ethical conduct of his experiments.

- This responsibility extends to assistants and colleagues.
- The investigator must secure the subject's informed consent to participate.
- Deception if used should be undone at the end of the experiment.
- Participants may not be coerced into participation and must be free to drop out at any point.
- Participants must understand the procedures to be employed.
- Subjects must be protected from physical harm and mental stress.
- The responsibility to correct undesirable effects of the experiment remains with the investigator after the experiment is over.
- Misconceptions and misunderstandings arising in the experiment must be removed.
- Complete confidentiality is required of all information obtained about participants.

This list provides the responsible investigator with a series of questions to ask himself about the treatment of participants in any experiment: "Do I have the subjects' informed consent?", "Is deception necessary?", and most importantly, "Have I and my colleagues and my assistants done everything we can to protect the welfare of our subjects as is required by the ethical code." Only if such an analysis of risks to the participant yields satisfactory answers does the ethical investigator proceed.

Subjects' assessment of risks. As was mentioned in an earlier section subjects in research typically are in no position to evaluate the costs of their participation until they have had the experience. Then it is too late by definition for this experience to contribute to a

decision about the ethical aspects of the research. This state of affairs does suggest one important point to make. Most investigations require a certain amount of pilot work. The few individuals who participate at this stage of the research might well be asked about their reactions to the experimental procedures for purposes of uncovering risks that may have escaped the analysis described above. Procedures could then be modified in directions designed to minimize these newly recognized risks

Institutional Review Groups. At least on university campuses the existence of Institutional Review Groups is an important scientific fact of life these days. In the typical case these groups are in a position to assess risks in the cases where the investigator may not be a "reasonable person" because of his investment in his research or an insensitivity to the feelings of subjects. In most situations even slightly sensitive projects come to these groups. In my own experience they almost always detect any problems the investigator has overlooked.

Summary and Comment

I have proposed that the risk/benefit equation be rewritten in realistic terms:

$$\frac{\text{Amount of Knowledge to Come from Research}}{\text{Risks as seen by Reasonable People}}$$

The major advantage of the rewritten equation is that it removes the necessity for making an impossible calculation. As we have seen many times now risks and benefits in the usual meaning of those terms present insurmountable obstacles to quantification. The terms as redefined seem to be susceptible to statements involving judgments of at least more and less. Although this is not exactly a precise formula for ethical decision

making I think that it is a step in the right direction.

I have left the main responsibility for making the risk/benefit calculation up to the investigator and have placed upon him two main obligations: 1) to be as sure as one possibly can that his research will lead to an advance in knowledge and 2) to assess the costs to participate and to minimize them.

I have rejected the alternative of assessing risks for individual participants because of the practical impossibility of the task and because such an assessment would surely invade the potential participant's privacy and would potentially lead to other ethical risks. Although the regress entered into in that way might not be infinite, the interesting thought does occur that, once started on such a process of detailing risks, it might be difficult to recognize the proper stopping place.

I have noted that the input of subjects might play a role in the investigator's assessment of risks. One could add to this point that taking such a view of the subject's participation might foster a sounder relationship than sometimes now exists between experimenter and participant.

Finally I have noted that Institutional Review Groups protect the subject's welfare at another level.

The Ultimate Risk/Benefit Equation

As a way of bringing this essay to an end I would like to return to the point with which I began and to direct the reader's attention to what might be called "the ultimate risk/benefit equation." In this equation the benefits are those which research will contribute to the solutions of the big problems of society. The risks are those entailed by not doing research at all and trusting to common sense and accumulated wisdom

to solve these problems. It seems to me that this alternative can be dealt with quickly. Common sense, intuition and accumulated wisdom have been with us forever. They seem to me to be as responsible as anything is for the sorry state the world is in now--where the disappearance of Man as a species is more than a fanciful abstract possibility. The time has come (if it has not passed) to turn to other sources of guidance and the only reasonable alternative is the knowledge provided by research.

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A PHILOSOPHICAL PERSPECTIVE ON THE ASSESSMENT OF RISK-BENEFIT
CRITERIA IN CONNECTION WITH RESEARCH
INVOLVING HUMAN SUBJECTS

Maurice Natanson, Ph.D.

A PHILOSOPHICAL PERSPECTIVE ON THE ASSESSMENT OF RISK-BENEFIT CRITERIA IN CONNECTION WITH RESEARCH INVOLVING HUMAN SUBJECTS

by Maurice Natanson

"The doctor said that so-and-so indicated that there was so-and-so inside the patient, but if the investigation of so-and-so did not confirm this, then he must assume that and that. If he assumed that and that, then...and so on. To Ivan Ilych only one question was important: was his case serious or not? But the doctor ignored that inappropriate question. From his point of view it was not the one under consideration, the real question was to decide between a floating kidney, chronic catarrh, or appendicitis. It was not a question of Ivan Ilych's life or death, but one between a floating kidney and appendicitis. And that question the doctor solved brilliantly, as it seemed to Ivan Ilych, in favour of the appendix, with the reservation that should an examination of the urine give fresh indications the matter would be reconsidered."

--Leo Tolstoy: The Death of Ivan Ilych

I. On the Relationship between Philosophy and Science

When philosophers discuss medical matters, there is a legitimate need to delimit their professional competence, for even when the issues involve ethical problems, it is by no means obvious that the philosopher is on solid ground in his inquiry. Just as the physician faces subtle and complex ethical difficulties in making some of his most important medical

decisions, so the philosopher confronts recalcitrant, technical medical issues which frequently transcend his training and understanding. The philosopher must rely largely on a reading of the literature on the subject; direct clinical experience is denied him. And, of course, what used to be called "recent advances" in medicine now give way to new fields of specialization. A few words (such as "genetic engineering") herald the ambiguities of a new age. The philosopher who yesterday may have been concerned about occasional pockets of scientific ignorance, today is overwhelmed by entire wardrobes of illiteracy. Elsewhere¹ I have briefly discussed some aspects of the need for the training of individuals who have some comprehension of both philosophy and medicine. That problem is not before us now, but its implications cannot be wholly overlooked. The fact is that what the philosophers know about ethics and what the scientists know about medicine seldom come together in a way which is satisfactory for either side, let alone for the social good. But the problematic relationship between philosophy and medicine may be seen as part of a more general rubric: the interdependence of philosophy and knowledge.

Rather than viewing philosophy and science as disparate disciplines which can be brought together only in artificial and cursory ways, it is possible to approach them as integral in their inner signification, as intimately related facets of the unitary reality of knowledge. Merleau-Ponty presents such a conception of unity:

"The segregation we are fighting against is no less harmful to philosophy than to the development of scientific knowledge. How could any philosopher aware of the philosophical tradition seriously propose to forbid philosophy to have anything to do with science? For after all the philosopher always thinks about something: about the square traced in the sand, about the ass, the horse, and the mule, about the cubic foot of size, about cinnabar, the Roman State, and the hand burying itself in the iron filings. The philosopher thinks about his experience and his world. Except by decree, how could he be given the right to forget what science says about this same experience and world? Under the collective noun 'science' there is nothing other than a systematic handling and a methodical use-- narrower and broader, more and less discerning-- of this same experience which begins with our first perception. Science is a set of means of perceiving, imagining, and, in short, living which are oriented toward the same truth that our first experiences establish an urgent inner need for. Science may indeed purchase its exactness at the price of schematization. But the remedy in this case is to confront it with an integral experience, not to oppose it to philosophical knowledge come from who knows where."2

In these terms, the physician who is making a decision regarding the life of his patient, the experimentalist who is seeking consent from a subject for a procedure which entails serious risk to that individual, the lawyer or governmental agent or advisor who is charged with the task of formulating codes for ethical conduct on the part of researchers which will assure appropriate protection of subjects for experimentation --all are tacitly involved in philosophical work. In addition to their connection with ethical matters, they are bound to try to appreciate the systemic unity of the domains of knowledge in which they operate. Philosophy is not something added to the recipe for knowledge; it is inevitably part of any effort to comprehend human experience. In this view, science and philosophy are both located within the unitary world which is experienced by all of us.

The point with which I am concerned is that ethics and ethical considerations cannot be extirpated from the corpus of philosophy in order to become useful to the scientist. More strongly stated, if ethical systems or judgments are extracted for specific scientific purposes, they may perhaps serve as heuristic guides for inquiry, but their full force will be diluted, if not destroyed. In my judgment, ethics is rooted in the soil of philosophy but cannot be handled in the way in which nurserymen secure trees for replanting. Ethical problems are fundamentally tied to conceptions of Man, of the human reality . We face an ambivalent situation with regard to the ethical aspect of medical experimentation on human beings because the physician, the scientist, and even the lawyer are apt to turn to ethics in the narrower rather than broader sense, i.e., they are searching for specific recommendations of what is ethical in a context whose basic moral nature is defined by the study of Man. I do not think that the needs of the researcher and of the social order which seeks to protect the individual can be served by divorcing ethics from philosophical anthropology --the effort to respond to the question What is Man? In fine, those analyses which are most likely to illuminate the underlying moral issues in experimentation on human beings are least likely to be the ones which offer concrete definitions, propositions, and calculi built out of such propositions in order to assist the formulator of ethico-legal codes. The paradox is that the more specific the ethical recommendation, the less chance there is for advancing the development of those primordial

philosophical analyses which can tell us something significant and lasting about ourselves.

The philosophical perspective from which I am writing is that of phenomenology and existentialism. More specifically, my fundamental approach to the problems which form the substance of this paper is indebted to the phenomenology of Edmund Husserl and Alfred Schutz and to the existential thought of Jean-Paul Sartre. I will avoid any attempt to summarize the essential doctrines of these thinkers, but a few words about their theoretical enterprise may prove useful to the reader. Husserl, Schutz, and Sartre disagree about important matters, but they are united in their concern with Man as the human reality, with Man as a being whose consciousness helps to build the microcosm in which he lives, and with Man as situated in the reality of daily life. Husserl speaks of the cardinal importance of the "Life-world," the stratum of mundane experience within which we locate our perceptual experience, our values, and our action. Schutz stresses the typified character of everyday existence, the projects of action through which ordinary human beings interpret their own and each other's meaning in the traffic of daily life. Sartre emphasizes the notion of situation itself. He writes:

"For us, man is defined first of all as a being 'in a situation.' That means that he forms a synthetic whole with his situation --biological, economic, political, cultural, etc. He cannot be distinguished from his situation, for it forms him and decides his possibilities; but, inversely, it is he who gives it meaning by making his choices within it and by it. To be in a situation, as we see it, is to choose oneself in a situation, and men differ from one another in their situations and also in the choices they themselves make of themselves. What men have in common is not a

'nature' but a condition, that is, an ensemble of limits and restrictions: the inevitability of death, the necessity of working for a living, of living in a world already inhabited by other men. Fundamentally this condition is nothing more than the basic human situation, or if you prefer, the ensemble of abstract characteristics common to all situations."3

In terms of the Life-world, man in daily life understands or misunderstands his situation in concrete ways, has a lucid or opaque sense of his own interests, and carries with him the resources of a sometimes acute and sometimes baffled intelligence. Yet it is within the range of those talents and debilities that he is compelled to construct and interpret the meaning of his experience. Scientific models of explanation of human conduct are abstractions of a very restricted and specialized sort which, so phenomenologists believe, must attend closely to and be responsive to the naive models of interpretation and action which common-sense human beings build out of their insight into and bewilderment with the materials of their own existence. In the realm of problems of risk and benefit in research and experimentation on human subjects, the resources and needs of the Life-world must not only be respected but must be studied in the most searching fashion, for what happens to all of us, ordinary men and women and physicians and researchers alike, remains rooted in mundane life and, ultimately, must be interpreted and evaluated by the categories of mundane rather than scientific experience.

II. The Concepts of "Risk" and "Benefit"

The notion of the Life-world provides a point of access to the understanding of risk and benefit because it makes it possible to distinguish between risk and benefit as quantifiable terms and risk and benefit as primary and endemic features of everyday experience. Of course, risk and benefit have an enormous range of reference. At one end of the spectrum, risk is a commonplace feature of the most taken for granted acts. As one writer points out, "...the baby could suffer fatal injury if dropped while being weighed."⁴ We shall be concerned with more substantial risk than that. At the same time, however, it must be recognized that whereas the formulation of risk (and benefit as well) is the professional responsibility of the investigator, whatever the formulation turns out to be must be interpreted by the subject or patient. What I am concerned with here is not simply the question of translating the language of the scientist into that of the layman. Presupposed in all such translation is the conceptual stance of the ordinary individual, the categories through which he comprehends the elements of his experience and their implications for his well being. Were the essential problem of "informed consent" just a matter of the effective restatement of technical language into straightforward, everyday language, the difficulties arising out of securing informed consent would disappear rather quickly. The difficulties are persistent because they are functions of something other than the mere efficacy of translation. In the instance of risk and benefit, the translation

of those terms and their implications into the Life-world of the patient or subject entails a primordial interpretation on the part of the individual who is doing the risking or expects to be benefited or have others benefited.

There are axioms of mother wit: there is no absolute assurance that what is reasonably expected will necessarily follow from an experiment; traditional and medically conservative measures may nevertheless produce undesirable effects in a particular case; benefit sought from a given procedure may carry along with it undesirable side effects; benefit to others may prove to be illusory or even detrimental; the relationship between what may be good for the individual and what may be good for society is generally uncertain, unstable, and revocable. Whether or not the individual formulates such axioms in the way I have, their import is naively grasped by everyone who wishes to avoid trouble, to preserve good health, and to survive under optimal circumstances. The axioms of mother wit are implicit assumptions which are part of the fabric of common sense. To be sure, there are some who are ignorant not only of elementary features of human anatomy and physiology but who are too timid to ask their doctors for more information. Not long ago, I read in a newspaper medical column a letter by a young man whose physician had told him that he had a spleen. How serious was that? the author of the letter wanted to know. There are also those who do not want to be told what the case is, what the possible dangers are, what the full implications of an experimental procedure might be. It is not possible here to proceed casuistically. Instead, I propose

to turn directly to the concepts of risk and benefit without losing sight of the notions of the Life-world and of situation.

A. Risk:

It is necessary to distinguish between risk for the individual undergoing treatment by his own physician or surgeon and risk for the individual who is being asked to participate voluntarily in an experiment in which he is to be a subject. The more pressing problems for our consideration appear to fall in the second classification, but the complex connection in therapy and experimentation between the two categories must be considered.⁵ To begin with, it is not unusual for writers on this subject to point to the problematic nature of the treatment-experiment relationship. As Maurice B. Visscher says, "...it is difficult to draw the line between what is experiment and what might be called medical treatment."⁶ Or as Herrman L. Blumgart puts it, "Every time a physician administers a drug to a patient, he is in a sense performing an experiment."⁷ But the same circumstance does not pertain in the distinction between, on the one hand, experimenting on one's patient for purposes directly related to trying to cure or alleviate his specific medical problems at a time when such therapeutic efforts are deemed necessary by the physician and, on the other hand, asking an individual to participate in an experiment from which he will not personally benefit in medical terms. Otto E. Guttentag recommends that "...a climate of spiritual values should be fostered in which experiments done

not for the immediate good of the experimental subject but for the welfare of mankind would be performed only by experimenters who are not simultaneously responsible for the clinical care of these experimental subjects."⁸ By separating physician in charge of the care of his patient from experimenter in control of his subject, it is hoped that the conflict of therapeutic-experimental interest may be avoided, though something of a paradox is generated in the process: the person best able to care for his patient is the physician; the person charged with the welfare of his subject --the experimenter-- is not primarily oriented toward caring for his subject.⁹

The paradox we have pointed to goes beyond the question of whether the clinician and the experimenter should have different roles with respect to patient and subject. The broader issue is the relationship between care, which is committed to the welfare of a concrete human being who is ill by a fellow human being, the physician, and treatment, which may indeed be all that is offered by some physicians whose interest in their patients is rather limited but which , in an experimental context, is tied to a different goal: the appropriate completion of the experiment. The risk to the experimental subject is far greater than the risk to the patient. Obviously, the degree of risk may, empirically, be reversed in the two situations under certain circumstances. The patient may be risking his life in a therapeutic procedure involving dangerous surgery, whereas the experimental subject may be submitting to routine and completely safe testing having to do with moderate changes in diet for a normal individual.

Indeed, the experimental subject may be part of a control group to whom nothing is done. But the paradox remains: when the patient becomes the subject, he needs more rather than less care, yet the risk of receiving that care from the experimenter is substantial. For the experimental subject who is not a patient, the risk is even greater. What, exactly, is risked? Most simply, that the well being of the subject is not the dominant concern of the experimenter, who may be more interested in the intellectual-scientific challenge of the experimental work itself, who may be strongly motivated by the expectation of publishing his results in the hope of advancing his professional career, or who may be unduly influenced by his colleagues in an experimental team. Such desires and pressures are not in themselves wicked and unethical; they are implicit hazards, however, for the subject who may assume that the experimenter places the well-being of his subject above personal gain.

B. Benefit:

In the case of the patient, benefit is directly correlated with the treatment of his illness. That is hardly to say that benefit is assured; it is only to say that what is being risked is being risked for the possibility of individual betterment. When it comes to the subject, however, benefit is correlated with a larger domain: those afflicted with a certain disease, those who would benefit if an effective and safe vaccine were developed for the inoculation of those who might develop a certain disease,

those who might benefit indirectly from knowledge gained in research on one medical problem which has or may prove to have relevance for another problem. Ultimately, society itself is said to benefit from the advance of medical knowledge. We shall say something about society and the individual shortly, but for the moment, it might be suggested that the concept of benefit is vague and fugitive to the subject in many cases and may serve as a shield not only to the experimenter whose medical ethics are questionable but also to the ethical experimenter who may be unwilling to face the full implications of a procedure which legitimates risking harm to one group of individuals for the sake of another group of individuals. Yet it would be unacceptable to reduce the meaning of benefit to patient-benefit alone. The decisive consideration is that benefit and risk be viewed in integral fashion. That means that what benefits human beings usually carries with it risk, and that risk which is deemed "minimal" or "acceptable" nevertheless may mean severe suffering or death to some. Chauncey D. Leake writes:

"There is no absolute safe and effective chemical agent that may be used for biological effects in humans, not even common table salt. The Gaussian distribution curve inevitably fits any drug, if it is used on enough people: in a few there may be no effect at all from the same quantitative dose that may produce serious injury or death in some. Here, social welfare must be considered, as when the Canadian authorities went ahead with mass protection against polio, using oral vaccine, although four people out of some 2,000,000 met death ascribed to it. Even a hedonistic ethic would take the chance of 1 in 500,000."10

A hedonistic ethic might very well accept the risk of 1 in 500,000, but we are left with the question of whether to accept a hedonistic ethic. In the case of the polio vaccine,

it is essential to recognize the nature and scope of the suffering and incapacitation of polio victims, the widespread awareness of the character of the disease, and the likelihood of permanently eliminating the devastating effect of polio on thousands of people. In assessing benefit, in this instance, there is a clear recognition of the quality and quantity of suffering and sufferers in the past. Benefit is directly related to the history of concrete and widespread anguish of victims and of those that love them. In the absence of such a history, it is prudent to reflect more thoroughly on the problem of justifying the death of some, however few, for the sake of the health of the many, no matter how many. The reasons which are accepted for justifying the risking of the life of the few are of critical importance in justifying the integrity and morality of the social order. In each case, those reasons must be intimately associated with the reality of suffering and the reality of sufferers. Furthermore, those reasons must be explained to both risk-takers and to those who desire them to take risks, to ordinary people and to physicians, experimenters, and, perhaps most important of all, to medical students and graduate students going into medical research. Not only giving reasons but defending those reasons in the context of the social order is essential to the protection and honor of all those who are involved in any way in experimentation on human beings.

If a casuistic analysis of risk and benefit problems lies beyond the scope of this paper, it would seem that all that can be recommended consists in generalizations which falter before the determination of concrete cases. Earlier, I pointed to the

desirability of a phenomenological-existential approach to the problems before us. What help can such an approach provide if specific determinations in concrete cases can only be loosely guided by general recommendations? In fact, the central difficulty in trying to find a way in the thickets of risk-benefit problems is that where detailed and highly specified protocols are issued, the physician and the experimenter who are highly ethical individuals may well be compelled, by constraint of law, to circumscribe their care and treatment of the patient and subject to the medical disadvantage of both risk-taker and the social good, whereas a more open and flexible set of guidelines may be misused in such a way as to injure or endanger the well being of the patient or subject and, in turn, threaten the moral fabric of society. Faced with a somewhat analogous paradox, the law tends to favor the more generalizing alternative. According to Paul A. Freund:

"As part of its conservatism, the law tends to generalize on the basis of a balance of risks. If, for example, it is thought that there is a predominant risk of perjury in claims that oral contracts have been made, the law enacts a statute of frauds requiring as a general rule, as an invariable rule, that there be a writing for important contracts, even though in some cases there is created a counterrisk that thereby some genuine oral agreements will not be recognized. If there is a predominant risk of suppressing information and criticism by enjoining the publication of allegedly libelous matter the law will make a general rule of refusal to enjoin, even though there is a countervailing risk that some actually defamatory matter will thereby be allowed to circulate. The law takes refuge in general rules as metaphysics resorts to absolutes."11

In the case of medical practice, viewed from an ethical perspective it is not evident that the analogy holds true. The law might require a written consent form in cases of experimentation, but

it is not clear what would constitute an "important" case, nor is it obvious what would be accepted as a "predominant" risk. Paradigms for "important" and "predominant" can usually be provided; but individual instances are uncertain and boundary cases are ambiguous. In any event, what is being risked and what is hoped for as benefit may be uncertain in the minds of both subject and experimenter. The paradox of concreteness and generalization continues to bedevil our discussion. But paradox need not lead to demoralization or to ethical paralysis; rather, it is the inescapable medium through which the tension between concreteness and generalization finds its expression.

III. The Needs of Society and the Rights of the Individual

The contrast between society and the individual may be understood as the contrast between the individual and other individuals. The common good cannot be divorced from the good of individuals. But the good of individuals presupposes a recognition of values which transcend the individual --let us call them moral values-- at the same time that they define the character of society. Society may embody and exemplify moral values, but it does not provide a ground for the legitimation of morality. Society is "moral" to the extent that it commits itself to the good of the individual, a good which transcends the individual for the sake of the individual. A double transcendence reveals itself here: the individual is transcended

insofar as moral values go beyond any one person's interests and needs, and society is transcended to the extent that the moral values it represents are not themselves justified on the sole grounds of the common good. During an epidemic, physicians and government officials have the right to segregate individuals who are likely to contaminate others, but that right (and obligation) does not carry with it an authorization to destroy those who endanger the lives of others. Certain rights of the contagious minority must be respected by the endangered majority. The moral value at issue here is that human beings are, by nature of their humanity, committed to the care of the afflicted. Should there be a situation in which the only way to protect the rights of the unafflicted is by destroying the afflicted, the social order would be challenged in its own moral inwardness. Nor is the moral tension eased if the minority involved is a tiny one. Hans Jonas writes:

"Society, in a subtler sense, cannot 'afford' a single miscarriage of justice, a single inequity in the dispensation of its laws, the violation of the rights of even the tiniest minority, because these undermine the moral basis on which society's existence rests. Nor can it, for a similar reason, afford the absence or atrophy in its midst of compassion and of the effort to alleviate suffering --be it widespread or rare-- one form of which is the effort to conquer disease of any kind, whether 'socially' significant (by reason of number) or not. And in short, society cannot afford the absence among its members of virtue with its readiness to sacrifice beyond defined duty."¹²

The rights and obligations of society toward its members and future members (and past members as well) are limited by its implicit as well as explicit commitment to the good of the concrete individual who seeks his physician's care. The physician

honors the good of society insofar as he respects the good of his patient. Apart from situations of pestilence, widespread starvation, natural disasters, or catastrophes of war where, for the time of the emergency, traditional commitments may be qualified or suspended, the needs of the patient have primacy. No equivalent primacy exists, in ethical terms, from the standpoint of society. It is misleading to emphasize the good of future members of society at the expense of present members. As Jonas puts it, "our descendents have a right to be left an unplundered planet; they do not have a right to new miracle cures. We have sinned against them if by our doing we have destroyed their inheritance....; we have not sinned against them if by the time they come around arthritis has not yet been conquered (unless by sheer neglect)."¹³ But it is evident that all physicians do not subscribe to this view. It is further evident that physicians who are fundamentally involved in research may interpret the society-individual relationship in a different way than physicians who are primarily concerned with caring for their patients. When the two overlapping categories coincide, some interesting problems arise. Renée C. Fox has presented a thorough description of the difficulties experienced by one team of research-physicians in determining the limits of ethical medical conduct in treating patient-subjects. She writes:

"The Metabolic Group was also engaged in a considerable amount of research which they undertook primarily to advance general medical knowledge, and only secondarily or incidentally because they thought it might be helpful to patients who consented to act as their subjects.

The members of the Group 'hoped' that the patients who participated in these experiments might gain some clinical benefit from doing so, and they were pleased when this happened. But to the limited extent that medical ethics allowed them to do so, they subordinated their clinical desire to serve the immediate interests of the particular patients involved in such experiments, and gave priority to the more long-range, impersonal research task of acquiring information that might be of general value to medical science."14

It is not easy to reconcile medical intervention done with a bare minimum of ethicality with serving the good of society. It would seem that such intervention has only a limited connection with the welfare of the patient-subject but a powerful relationship to the abstract development of medical knowledge.

I do not think that an ethical balance can be struck between the needs and rights of the individual and the needs and rights of society if what is relinquished in the former is the trust that tacitly undergirds the relationship between patient and physician or if what is compromised in the latter is the morality which is based on the inviolability of human freedom. In fact, the very notion of "balance" in this context is unacceptable if it leads to a "give and take," a "more or less" of qualitative human assurances which are irreducible and, in principle, incapable of being negotiated in terms of a quantitative calculus. One such human assurance is the patient's right to expect that anything done for him is being done in his interest, as that interest is interpreted by the physician who cares for him. In the case of the subject-experimenter relationship, the fundamental human assurance is that the most honest, non-selfserving effort has been made in a well-designed experiment to inform the subject clearly and with appropriate fullness about what will go on in the

experiment, about what known dangers there may be, about the possible injurious side effects that are deemed plausible, or about the vaguer risks which are being taken by the subject, given the status of what is not known about the possible results of the procedure at issue. The words "appropriate fullness" may seem to beg the question. The acceptability of the phrase depends ultimately on the honesty of the person who seeks "informed consent" from the subject. "Honesty" hardly implies omniscience; it does imply that the subject's good is not given secondary consideration merely because he has volunteered for the job. In the case of patient-subjects, appropriate fullness demands of the physician-experimenter that serious risk be taken only when the patient-subject's welfare is of primary concern. As Henry K. Beecher states:

"Considerable or even great risk is not necessarily an absolute injunction against acceptance by the investigator or the subject. Indeed, some procedures have been associated with a fatal outcome and yet may still provide advantages great enough to outweigh the hazard involved. One cannot forbid what may be a perilous procedure on the basis of unknown risk alone. It seems to me, however, that great risk should usually be accepted only if the subject promises to profit directly from it."¹⁵

We are still left with the category of fully informed, consenting subjects (including some patient-subjects) who volunteer for potentially hazardous experimentation from which it is unlikely that they can derive any personal medical benefit. Granted the problematic status of the notion of "informed consent,"¹⁶ it is still possible to say that among the rights of individuals is the right to serve as a volunteer in an experiment which may benefit others. However, society is obliged to guard against abuse by

experimenters of the rights and needs of those who are most vulnerable to unethical conduct by those doing research: the sick, the old, the retarded or mentally ill, children, prisoners, the impoverished, and those whom life has neglected or betrayed. Perhaps it is not really possible to arrive at an absolute statement of the sufficient conditions for fully informed consent, but it is possible to state more comprehensively the necessary conditions which must be met.¹⁷ Medical codes, guidelines, and protocols already exist which serve to protect both subjects and experimenters, but the inevitable paradox of the concrete and the abstract arises once it is asked how a general recommendation or requirement can be applied in a specific case, Henry K. Beecher warns:

"There is the disturbing and widespread myth that 'codes' (all of which emphasize, above all else, consent) will provide some kind of security. While there is value, doubtless, to be gained from their examination as guides to the thinking of others on the subject, the reality is that any rigid adherence to codes can provide a dangerous trap: no two situations are alike; it is impossible to spell out all contingencies in codes. When an accident occurs, in the course of experimentation, it will be easy for the prosecution to show failure to comply fully, and an endless vista of legal actions opens up. It is a curious thing that lawyers for even the greatest institutions are much more likely, in my experience, to cripple themselves and their institutions with inevitably imperfect codes than are the investigators involved, who usually understand the pitfalls represented by the codes. Security rests with the responsible investigator who will refer difficult decisions to his peers."¹⁸

Nevertheless, such documents as the Nuremberg Code and the Declaration of Helsinki do more than provide a guide "to the thinking of others on the subject"; they embody and represent commitments to moral value which make it possible for both investigators and subjects to recognize and affirm in these

formulations the conditions of treatment of and concern for fellow human beings. The ideality of the codes does not detract from their primary purpose.

Unethical, irresponsible, or incompetent investigators (or those who choose to exceed their domain of competence) cannot be legislated out of existence, but they can be constrained by the criticism of those who are ethical, responsible, and expert. It has been pointed out that editors of medical journals have a particular responsibility to exert caution in evaluating articles submitted for publication which are based on data which were unethically obtained.¹⁹ Such caution should make it more difficult for those whose announced plans for experimentation were found acceptable by their colleagues and superiors but whose actual practice exceeded ethical standards. Knowing in advance that important results unethically obtained will not be published will tend to restrain the unethical investigator. More difficult to cope with is the situation of the experimenter who does commit himself to the constraints of ethical practice but who finds it extraordinarily difficult at times to treat subjects as moral ends without denying them and others the utilization of perilous means. The physician-investigator in particular is haunted by the desire to stand by his patient while also honoring his commitments to the advancement of medical knowledge. As I have already suggested, there is no calculus which can substitute for determining the qualitative good of human beings.²⁰ To say that, however, is not to claim that such a calculus cannot be constructed; it is only to warn that any

calculus must ultimately be interpreted by human beings and that the act of interpretation presupposes qualitative factors which have been incorporated in the initial construction of a mathematical model as well as the qualitative character of the act of interpretation itself. No doubt, a computer could be programmed in such a way as to pick out the best candidates for an experiment; the choice of those candidates, however, needs to be made by a human being who is morally obliged to reflect on the meaning of "best candidates" not only for the benefit of the experimenter but also for the welfare of the candidate. A computerized blood bank is an extraordinarily useful instrument, but it tells us nothing about what is morally demanded of those in charge of it.

IV. On Dignity and Philosophical Method

Discussions of experimentation on human beings and codes which seek to protect the individual against unethical conduct on the part of physicians and experimenters frequently stress the importance of honoring the dignity of the person. So, for example, the Principles of Medical Ethics of the American Medical Association includes the following dictum: "The principal objective of the medical profession is to render service to humanity with full respect for the dignity of man."²¹ Or as Herrman L. Blumgart expresses it, "A person has a right not only to live in dignity, but also to die in dignity."²² Between the affirmation of such norms and the reality of medical practice (which, in turn,

reflects the reality of societal demands and commitments) lies the dark terrain of actual practice: the realm of second and third-rate medical treatment performed by mediocre and sometimes incompetent staff in hospitals and offices which are often teeming with people whose "dignity" is of little consequence to those who are supposed to "care" for them. The more immediate concerns are being able to handle the flow of emergency cases, ascertain the patient's ability to pay for services to be provided, and sustain basic services under distressing circumstances. Being able to attend to the patient's dignity in such conditions may be viewed as a luxury. In any event, the medical microcosm mirrors the macrocosm of society, where dignity is an ideal which is often subverted by bad faith. Guido Calabresi points out:

"Accident law indicates that our commitment to human life is not, in fact, so great as we say it is; that our commitment to life-destroying material progress and comfort is greater. But this fact merely accentuates our need to make a bow in the direction of our commitment to the sanctity of human life (whenever we can do so at a reasonable cost). It also accentuates our need to reject any societal decisions that too blatantly contradict this commitment. Like 'free will,' it may be less important that this commitment be total than that we believe it to be there.

Perhaps it is for these reasons that we save the man trapped in the coal mine. After all, the event is dramatic; the cost, though great, is unusual; and the effect in reaffirming our belief in the sanctity of human lives is enormous. The effect of such an act in maintaining the many societal values that depend on the dignity of the individual is worth the cost. Abolishing grade crossings might save more lives and at a substantially smaller cost per life saved, but the total cost to society would be far greater and the dramatic effort far less. I fear that if men got caught in coal mines with the perverse frequency with which cars run into trains at grade crossings, we would be loath to rescue them; it would, in the aggregate, cost too much."²³

Surely, affirming the dignity of the patient is axiomatic for his

doctor, but unless the affirmation carries existential force along with it, its axiomatic status means that it is simply taken for granted and that its ideal or normative character remains distant from specific application. No one wishes to be on record as opposing the dignity of man, but approving that sentiment hardly calls for much unless it requires moral practice in which case, its demands are profound.

If there is bad faith in society, it does not follow that there must be bad faith in individual choice. If society "chooses" to do something about the individual and relatively uncommon but dramatic case of the trapped miner rather than the more widespread tragedy of collisions at grade crossings, it is not because the dignity of one victim is more compelling than the dignity of another victim. As Calabresi indicates: "The notion is incorrect that we in some sense choose the number of people who will be killed in automobile accidents by choosing a market system that will determine how much safety is worth. The notion is only made plausible by a verbal trick --by using the words 'we choose' to describe both the effects of the social system in which we live and which we tolerate, but which we cannot in fact be said to choose, and events as to which we can be said to exercise purposive choice."²⁴ But in the case of experimentation, choice does lie with experimenter and subject. Experimentation is purposive choice. Accordingly, the experimenter, unlike society at large, is obliged to respect the dignity of the concrete human beings who come within his professional purview. Just what does dignity signify in this context? We have returned not

only to a philosophical issue but, in a way, to the philosophical approach which we outlined so hastily at the outset of this inquiry and to the status of the central terms of discourse which have arisen in the course of our discussion. It is time to attend further to those problems of philosophical method which underly our comprehension of the nature of Man.

When we say that it is the professional responsibility of the physician to care for his patient or when we say that the dignity of each patient must be respected, we are making trans-empirical recommendations. The care provided by a physician to a patient may, in a narrow sense, be reviewed by others; but that only means that services are being scrutinized. Care, as we have been using the word, refers to the commitment the physician has made as a fellow human being to another fellow human being who is in need. Care in this sense is recognized by those who are immediately involved in the situation of care: physician, patient, and others who are truly concerned with the well-being of the patient. In a similar way, respect for and recognition of human dignity is a function of the individual relationship between physician and patient. Both care and dignity do not preclude therapeutic distance on the part of the physician; indeed, such distance is necessary if he is to function effectively. But distance does not either damage or replace devotion and dedication. If care and dignity are transempirical in nature, it does not follow that they are incomprehensible either to the patient, the physician, the subject, or the experimenter. To the contrary, care and dignity are terms whose meaning is rooted in

the Life-world and whose appreciation, therefore, is available to ordinary men and women and children. To be treated with respect and decency is the common desire of all of us. To ignore the dignity of the person or to treat him without really caring for him results in human resentment. That such commonplaces are recognized and affirmed by common-sense people is precisely the point of self-interpretation within the Life-world. We recognize as mundane creatures that although we may be replaceable as organisms, our identities as persons are not commodities. To care for and respect the person has little to do morally with liking the individual, whatever the psychological relationship may be between physician and patient. Rather, care and respect are directed toward the privileged being of the person. James Agee writes:

"Each is intimately connected with the bottom and the extremest reach of time:

Each is composed of substances identical with the substance of all that surrounds him, both the common objects of his disregard, and the hot centers of stars:

All that each person is, and experiences, and shall never experience, in body and in mind, all these things are differing expressions of himself and of one root, and are identical: and not one of these things nor one of these persons is ever quite to be duplicated, nor replaced, nor has it ever quite had precedent: but each is a new and incommunicably tender life, wounded in every breath, and almost as hardly killed as easily wounded: sustaining, for a while, without defense, the enormous assaults of the universe."25

The same integrity between care and dignity must be retained or at least struggled for in the relationship between experimenter and subject. It is possible that unethical means may yield potentially beneficial results; it is certain, however, that the

deliberate choice of unethical means will damage the conditions of trust between human beings which constitute the realm of moral ends. When I said earlier that the relationship between risk and benefit must be viewed in integral fashion, what I meant was that the concrete situation of the individual within the social order (including its historical dimension) commands fundamental respect. Understanding that situation means holding in tension the way in which the individual interprets the meaning of his own action and the manner in which society comes to self-recognition through the moral choices made by its agents. When the subject-volunteer is genuinely and thoroughly informed, when he knows that the considerable risk he agrees to take cannot benefit him personally as far as his health is concerned, and even when he considers himself a co-worker with the experimenter in the cause of general scientific knowledge, still there remains a moral (though not an ethical or legal) constraint on the investigator to do his best by a fellow human being, to minimize or to try to control whatever pain the subject may receive, and to do everything reasonably and appropriately possible to guard against damaging or fatal consequences. Perhaps the most difficult task the experimenter faces is to refuse to capitalize on the good will and trust of his subject for the sake of the experiment. I remain haunted by a fragment from a physician-experimenter's case history: "This amiable and cooperative gentleman, having previously been prostatectomized, orchidectomized and adrenalectomized, reenters to be nephrectomized."²⁶ It is remarkable how this gentleman's amiability has managed to keep pace

with his cooperativeness, for his prostate, testicles, and adrenal glands have been removed, and he now faces the further surgical loss of a kidney. What a sadly punishing history remains locked in that medical sentence.

My conclusion can be presented in straightforward terms. An appreciation of the structure and texture of the Life-world, of the meaning of human action in mundane experience, and of the fundamental situatedness of persons within the world is essential to the determination of risk and benefit relationships in all experimentation on human beings. A phenomenological and existential approach to these problems offers a valuable point of access to the interpretation of the nature of medical care and human dignity. Any assessment of risk-benefit criteria must remain grounded in the moral imperatives of human beings seeking to fulfill themselves in their dependence upon their fellow human beings. The abstractness and generality of moral claims cannot be reduced to quantitative models for medical decision without eroding the very goals of a just social order in whose name experimentation is carried on. Care and dignity are not euphemisms for unrealistic demands; they are the substance of our moral energies and the means through which we express the paradox-ridden career of man in the social world.

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NOTES

1. Maurice Natanson, Phenomenology, Role, and Reason (Ch. XIV, "Benefit and Experimentation"), Springfield, Ill.: Charles C. Thomas, 1974, pp. 304-306.
2. Maurice Merleau-Ponty, Signs (trans. with an Introduction by Richard C. McCleary), Evanston, Ill.: Northwestern University Press, 1964, pp. 101-102.
3. Jean-Paul Sartre, Anti-Semite and Jew (trans. by George J. Becker), New York: Schocken Books, 1948, pp. 59-60.
4. Henry K. Beecher, "Medical Research and the Individual," in Life or Death by Edward Shils and others (Introduction by Daniel H. Labby), Seattle: University of Washington Press, 1968, p. 124 (note: Beecher attributes this observation to R. A. McCance).
5. Jay Katz makes an important point in this connection: "Distinctions have traditionally been drawn between research conducted by investigators on 'normal volunteers' in purely experimental settings and by therapist-investigators on 'patients' in treatment settings. It has generally been assumed that more stringent controls should be placed on investigators whose actions are designed to gain knowledge rather than to promote the subject's 'best interests.' Yet in most situations it is difficult to draw lines between 'normal volunteers,' 'patient-subjects,' and 'patients.' Moreover, the therapeutic setting may be the one which deserves the closer scrutiny. While a volunteering subject can be alert to protect his own self-interest, a patient-subject's need for treatment may cause him to overrate the benefits and underestimate the risks of a research technique." (Experimentation with Human Beings, New York: Russell Sage Foundation, 1972, p. 727).
6. Maurice B. Visscher, Ethical Constraints and Imperatives in Medical Research, Springfield, Ill.: Charles C. Thomas, 1975, p. 64.
7. Herrman L. Blumgart, "The Medical Framework for Viewing the Problem of Human Experimentation," Daedalus, Vol. 98, No. 2, Spring 1969, p. 253.

8. Otto E. Guttentag, "Ethical Problems in Human Experimentation," in Ethical Issues in Medicine (ed. by E. Fuller Torrey), Boston: Little, Brown, 1968, p. 212.

9. Dr. Guttentag is sensitive to the therapeutic imbalance which may result from the effort to protect the needs of the patient as well as the experimental subject. He writes (ibid., pp. 200-201): "With reference to the relationship between experimenter and experimental subject, it is the concept of partnership between the two, resulting from the fact of their being fellow human beings, that reflects our basic belief and cannot be subordinated to any other." Cf. Joseph Fletcher, Morals and Medicine, Boston: Beacon Press, 1960, p. 37.

10. Chauncey D. Leake, "After-Dinner Address: Ethical Theories and Human Experimentation," Annals of the New York Academy of Sciences, Vol. 169, Art. 2, January 21, 1970, p. 394 (note: this is an issue on "New Dimensions in Legal and Ethical Concepts for Human Research"). Cf. the following statement by Henry K. Beecher: "...in discussing new and uncertain risk against probable benefit, Lord Adrian spoke of the rise in Britain of mass radiography of the chest. Four and a half million examinations were made in 1957. It has been calculated that bone marrow effects of the radiation might possibly have added as many as 20 cases of leukemia in that year; yet the examinations revealed 18,000 cases of pulmonary tuberculosis needing supervision, as well as thousands of other abnormalities. The 20 deaths from leukemia were only a remote possibility, but, Lord Adrian asks, if they were a certainty would they have been too high a price to pay for the early detection of tuberculosis in 18,000 people? (in Updating Life and Death (ed. by Donald R. Cutler), Boston: Beacon Press, 1969, pp. 239-240.

11. Paul A. Freund, "Ethical Problems in Human Experimentation," in Readings on Ethical and Social Issues in Biomedicine (ed. by Richard W. Wertz), Englewood Cliffs, N.J.: Prentice-Hall, 1973, p. 38.

12. Hans Jonas, "Philosophical Reflections on Experimenting with Human Subjects," Daedalus, Vol. 98, No. 2, Spring 1969, pp. 228-229.

13. Ibid., pp. 230-231.

14. Renée C. Fox, Experiment Perilous, Glencoe, Ill.: Free Press, 1959, p. 46 (note: The continuation of the passage from which this quotation is taken deserves special attention (pp. 46-48)): "The following are the basic principles governing research on human subjects which the physicians of the Metabolic Group were required to observe in order to 'conform to the ethics of the medical profession generally...and satisfy democratic morality, ethics and law':

1. Voluntary consent of the subject is absolutely essential. Consent must be based on knowledge and understanding of the elements of the study and awareness of possible consequences. The duty of ascertaining the quality of consent rests on the individual scientist and cannot be delegated.

2. The experiment should seek some benefit to society, unobtainable by any other method.

3. The experiment should be designed and based on prior animal study, the natural history of the disease or problem and other data so that anticipated results may justify the action taken.

4. It should be conducted to avoid unnecessary physical and mental suffering.

5. No experiment should be undertaken where there is reason to believe that death or disability will occur, except perhaps where the experimenter may also serve as his own subject.

6. The degree of risk should never exceed that which the importance of the problem warrants.

7. There should be preparation and adequate facilities to protect the subject against even remote possibility of injury, disability or death.

8. Only scientifically qualified persons, exercising a high degree of skill and care, should conduct experiments on human beings.

9. The subject should be permitted to end the experiment whenever he reaches a mental or physical state in which its continuation seems to him impossible.

10. The investigator must be prepared to end the experiment if he has reason to believe that its continuation is likely to result in injury, disability or death.

The physicians of the Metabolic Group were deeply committed to these principles and conscientiously tried to live up to them in the research they carried out on patients. However, like most

norms, the 'basic principles of human experimentation' are formulated on such an abstract level that they only provide general guides to actual behavior. Partly as a consequence, the physicians of the Metabolic Group often found it difficult to judge whether or not a particular experiment in which they were engaged 'kept within bounds' delineated by these principles.

This was especially true of the experiments they conducted primarily to advance medical knowledge. The justification for this kind of research did not lie in its potential immediate value for the patients who acted as subjects. Rather, it was premised on the more remote, general, uncertain probability that its 'anticipated results...their humanitarian importance...for the good of society' and the chance of achieving them --would exceed the immediate amount of 'suffering' and 'risk' the experiment might entail. The criteria on which physicians ought to form such a calculus are not specified by the rules of conduct for clinical research. Thus, without many established or 'clean-cut' bases of judgment to guide them, the physicians of the Metabolic Group were constantly faced with the problem of trying to decide whether the particular experiments they were conducting fell within the limits of their rights as investigators, or whether they were overstepping those rights by subjecting the patients involved to more inconvenience and danger than the possible significance of those experiments for the 'advancement of health, science, and human welfare' seemed to warrant."

15. Henry K. Beecher, "Medical Research and the Individual," p. 124

16. Henry K. Beecher says: "Again and again I think we are deceiving ourselves if we think we can very often get satisfactorily informed consent. It's the goal toward which we strive, and in striving for it we get a positive value. The positive value is that the subject knows, because of your inquiry, that he is going to be the subject of an experiment. I can tell you hundreds of examples where they haven't known that they were subjects sometimes of deadly experiments, and so I think there is a value in striving toward this goal. But we are deceiving ourselves if we think we ever achieve it in ordinary circumstances, in any reasonably complex situation." (in Ethical Issues in Biology and Medicine (ed. by Preston Williams), Cambridge, Mass.: Schenkman, 1973, p. 225.

17. See the material on informed consent included in Jay Katz's Experimentation with Human Beings. In Experiment Perilous, Renée C. Fox provides the following information about consent (p. 112): "Sometimes the Metabolic Group obtained the informal, spoken consent of the patients who participated in their experiments. However, for those which involved a considerable amount of hazard and risk, they usually had the patients involved (or their closest of kin) fill out the following form:

I, _____, hereby certify that I have had explained to me the details of the contemplated procedure and assume full responsibility for any results of such a procedure.

Signed _____
Date _____

Witnessed

Putting the patient in possession of technical information not only protects his welfare; it also fulfills the moral prescriptions of science, and, in so doing, helps to perpetuate and give momentum to scientific investigation as an institution. There is evidence to indicate that when these moral precepts are violated, scientific creativity is impaired."

18. Henry K. Beecher, "Consent in Clinical Experimentation-- Myth and Reality," in Experimentation with Human Beings, p. 583.

19. See Henry K. Beecher, "Medical Research and the Individual," p. 150.

20. Robert J. Levine is right in hesitating to recommend the use of mathematical models in determining risk-benefit relationships. In addition to the difficulty he points out in assigning a weight or probability to the experience of pain, there is the question of how a mathematical model, once established, can interpret or help us to interpret the concrete situation of the patient or subject in a world defined not only by the experimenter but, in the first and last instance, by the patient himself. See Levine's manuscript of October 27, 1975 on "The Role of Risk-Benefit Criteria in the Determination of the Appropriateness of Research involving Human Subjects" (prepared for The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research).

21. Quoted by Richard C. Allen in Readings in Law and Psychiatry (ed. by Richard C. Allen, Elyce Zenoff Ferster, and Jesse G. Rubin, Baltimore: The Johns Hopkins Press, 1968, p. ix.

22. Herrman L. Blumgart, "The Medical Framework for Viewing the Problem of Human Experimentation," p. 272.

23. Guido Calabresi, "Reflections on Medical Experimentation in Humans," Daedalus, Vol. 98, No. 2, Spring 1969, pp. 388-389.

24. Ibid., pp. 391-392.

25. James Agee and Walker Evans, Let Us Now Praise Famous Men, Boston: Houghton Mifflin, 1941, p. 56.

26. Renée C. Fox, Experiment Perilous, p. 44.

ESSAY ON SOME PROBLEMS OF RISK-BENEFIT
ANALYSIS IN CLINICAL PHARMACOLOGY

Lawrence C. Raisz, M.D.

Risk-Benefit Analysis is an extension of common sense decision making. Faced with any alternative, a rational individual will determine what the advantages and disadvantages of each particular course might be and then proceed. When such an analysis is extended from single individuals to physicians as investigators and patients as experimental subjects, and particularly when the analysis involves matters of life or death, health or well being and legal sanction or disapproval, the analysis becomes more difficult and common sense will not suffice.

This paper will focus on the particular case of the development and evaluation of drugs to be used in the treatment of human disease. The following special problems must be considered:

- 1) In the first phase of drug development in man, the individuals who take the risks, that is, who are given the drug, are not those who will benefit from its subsequent use. In phase I clinical trials, normal subjects are given a drug to examine its pharmacokinetics and look for any unexpected adverse effects which have not been detected in animal testing.
- 2) In phase II, when the drug is first administered to patients, these patients will be selected on the possibility that the drug is effective in their disease. However, there is no statistical basis on which to guess the likelihood that the effect will be desirable.
- 3) While we assume that risks and benefits should be assessed in terms of weighing statistical probabilities, there are always numerically undefinable qualitative differences which must be taken into account.

For example, a much lower per cent likelihood of a fatal reaction is acceptable for an agent used to treat a non-fatal illness compared with a drug used to treat a fatal illness. In our analysis we must assess what per cent of skin rashes should be the equivalent of what per cent of episodes of blood dyscrasia. This problem is compounded by the fact that the numbers of subjects are usually so small that the statistical inferences can only be made within very broad confidence limits. This is particularly true for infrequent but serious adverse drug reactions. Historically such reactions have never been fully appreciated until an agent has been marketed and used in large numbers of individuals for some years.

4) Finally, risk-benefit analysis should include assessment of the risks attendant upon failure to develop a new agent or procedure, and the loss of benefits due to delays in developing an agent or impediments in making it available for general use. In terms of national and world health this is certainly numerically the most important kind of failure of any health system to bring its maximum benefits to the greatest number of individuals.

In Section I of this paper, I will discuss the first problem in some detail. Section II will touch on other aspects more briefly. My point of view will be that of a clinical scientist; the concepts and examples will be derived from the diagnosis and treatment of "organic" illnesses, that is excluding psychologic research and therapy of psychiatric illness

in which I have had no personal experience.

I. Is it valid to apply risk benefit analysis when the riskers and the beneficiaries represent totally different populations?

A simple answer to this question might be, "No, but we have to do something like it, so let's get on with the job." In a phase I clinical trial there must be prior toxicity studies in animals, sufficient to predict an extremely small risk of permanent physical injury, particularly of death, at the doses initially administered in man. Nevertheless, these risks can never be reduced to zero. The question at issue is to what extent and with what safeguards will human volunteers be allowed to take such risks for the benefit of others. While differing enormously in practice, in principle, religious sacrifice to appease the gods had the same motivations and was intended to serve the same needs of society. Societies which performed sacrifices believed that they would receive important benefits in the form of more rain, better crops, or victory in war. We expect to receive benefits in terms of better health by having humans take experimental risks. One major difference is that the scientific method should enable us to determine, after the fact, whether the expected benefits were actually obtained and whether the risks in our use of human volunteers were actually small. A second difference is that in primitive societies suffering was considered necessary for sacrifice to be effective while the goal in human research is the avoidance or mitigation of human suffering.

However, one point which is emphasized by recognizing the common conceptual ancestry is that "not all volunteers are really volunteers." The Mayans sacrificed prisoners of war; we ask prisoners of society to volunteer for phase one trials. This does not make the use of prison volunteers in phase one trials indefensible. We consider ourselves to be an essentially moral society, so, I suspect, did the Mayans. The difference lies in the value placed on human life and freedom. Hence, to satisfy our moral tenets, we must believe that prisoner volunteers are true volunteers. If a prisoner can obtain decent food and housing, proper treatment from custodians, or consideration for early parole only by volunteering then there is coercion. If the only difference between a prison volunteer and a non-volunteer is a small compensation for the time and discomfort involved then the system may be truly voluntary. The gap between morally defensible and morally indefensible may seem large but as with all such polarities there are many gradations in between and these can change with time. This is apparent when considering some of the abuses in human experimentation which lead to our present concern. Experiments involving the injection of cancer cells and delays in antisyphilitic therapy seem morally indefensible now, but were presumably considered defensible by those who carried out or approved them. If one examines the records of hospital human investigation committees one can find evidence of changing criteria - recently these have been largely in the direction of greater concern for the safety and freedom from coercion of experimental subjects. The fact that

prisoners eagerly volunteer to be experimental subjects does not resolve the moral issue. In fact it may indicate how strong the element of coercion is, that is the degree to which becoming a subject for a phase one trial is advantageous to the prisoner and not volunteering is disadvantageous. If so much benefit accrues that it would be better to take a substantial risk of physical harm than not to volunteer there is something wrong with the penal system.

A special case in which the individual taking the risk is less likely to receive any benefit is the clinical trial in which a placebo or dummy treatment is used. It could be argued that this is no longer an important issue in clinical pharmacology since drugs which have been shown to be better than a placebo are now available to treat a wide variety of subjective symptoms. Hence, any new agent should be compared with the best agent previously available for that symptom or disease; and thus both the treated and control groups would be likely to benefit. Except for trials which are designed to assess minor, quasi-therapeutic effects, such as a study to determine whether caffeine really helps students stay awake while studying, or trials on agents which may have small or subtle effects on mood or behavior, the use of placebos is becoming less necessary and less justifiable in therapeutic research. Probably the most important current need for placebo controlled trials is in the areas where they are unlikely to be undertaken because of practical difficulties or societal condemnation. For example, it might be worthwhile to repeat, using

modern techniques, a study done years ago in which a group of patients were subjected to surgery intended to increase coronary perfusion and a control group actually underwent a dummy operation. The current solution is to have the control group treated medically, not subjected to a placebo operative procedure. While this is more easily defensible on moral and practical grounds, it may well be that the effectiveness of expensive coronary bypass surgery will be experimentally validated not because of its cardio-vascular effects, but because an operation has an extremely powerful placebo effect.

The principles for obtaining volunteers from other closed populations such as students, military personnel or patients in chronic care facilities, should be similar to those for prison volunteers. For students it is particularly important to separate the roles of teacher and evaluator from that of investigator so that students will not feel constrained to volunteer to get better grades or recommendations from faculty members. Clearly the best method for obtaining volunteers would be by recruiting from society at large, using appropriate advertisement. Even if volunteers are truly free, there remains the additional problem of determining whether some should be prevented from volunteering "for their own good". This involves both philosophic questions of the limits of individual freedom and psychiatric questions of the evaluation of mental competence. Society often errs on the side of excessively restricting individual freedom to volunteers and undervaluing the mental competence of its members.

If consent is truly informed and risks are minimized, then it seems inappropriate to deny the right to volunteer because of what is judged to be an inappropriate personality or insufficient mental competence. The critical judgement should be whether informed consent is based on sufficient information which is sufficiently comprehended. Theoretically it is possible to inform individuals who are mentally ill, below the age of legal consent, or have relatively low intelligence or little education, provided that the means are appropriate. This is simply an extension of the general problem; to obtain informed consent one has to provide information in terms that can be understood by the individuals asked to give consent. If there is no communication there can be no informed consent. One cannot obtain consent from fetuses or infants or patients in coma.

There remains the most difficult question; whether anyone can decide that non-consenting human subjects should be used for an experimental procedure. I believe that proper mechanisms for such experimentation must be developed because important advances in the prevention and treatment of human disease sometimes cannot be achieved by any other means. However, the usual mechanisms of review by the institution coupled with informed consent by the parent or guardian are not sufficient. A judicial state or federal review procedure is required to determine whether the benefits are sufficiently large, the risks sufficiently small and most important, whether there is no alternative method of obtaining the desired information.

In a phase I trial on volunteers who are not expected to benefit from the agent being examined, the usual criteria for informed consent may not really be relevant. Neither the probability nor the nature of adverse effects is truly known. Information can be given based on animal trials but its uncertainty must be emphasized. On the other hand, it does seem appropriate to tell the volunteers in a study what the expected benefits to the other members of society might be. In other words, any volunteer should have the privilege of knowing why they are being asked to take a risk, and be treated with the dignity and respect that one should accord an active participant in the research process. If the prospective volunteer doesn't think a risk is worth taking for the benefit being sought this should be sufficient reason for them to refuse to participate.

Even when volunteers are free to give or withhold properly informed consent, a different procedure may be required to assess the risk-benefit equation simply because the riskers and beneficiaries are different individuals. It may help to carry out the initial assessment of risks and benefits separately before looking at them together for comparative weighing. There are several reasons for this. First, the assessment of risk may involve different forms of expertise and certainly involves different societal considerations than the assessment of benefit. Second, the risk-benefit equation cannot be balanced internally by a single institutional review committee. The risks will be taken in one institution but the benefits will accrue outside it. Of course, in any experiment there is potential benefit to individuals and society outside the purview of the

institutional review group, but some potential beneficiaries will be in the institution and the review group will have some understanding of these problems or access to local experts who do. Where the benefits are external, separate expert consultants and advocates are needed to assess the potential benefit of the research.

In assessing the risks for a volunteer group in a phase one trial one needs information from animal studies and an analysis of potential risks based on the experience of clinical pharmacologists whose special area of competence is adverse drug reactions. In addition, the volunteers need an advocate both to assure their general rights and to ascertain that there is no coercion. In assessing the benefits there should be input not only from those who are sponsoring the drug, but also from disinterested experts, in the therapy of the disease or condition for which the drug is intended who can testify as to the degree of need for additional or new therapy and the likelihood that the therapy to be tested will fill that need. An additional advocate who represents the patient population at risk should have input. The final review must assess the material on risk and benefits coming from different sources and attempt a balance. This should be carried out by a group which is not only broad in composition, but includes individuals who are independent of the institution where the initial research is carried out. Appropriate mechanisms could be developed at the community, state or federal level. The level used might depend on the nature and magnitude of the project. Ideally multiple levels should be available for

appeal. At present review is carried out at the federal level by the Food and Drug Administration. The mechanisms are over-centralized, sometimes cumbersome and community and societal interests, particularly these of potential beneficiaries, may not be fully appreciated. It seems inappropriate to ask the FDA to add to its already heavy administrative load such an extensive consideration of the ethical, moral and social issues which are so often involved in clinical trials. The formation of a separate national review body might be a logical extension of the work of the National Commission.

The tripartite approach discussed above may sometimes also apply to risk benefit analysis in studies of non-therapeutic procedures. While not ordinarily considered a part of clinical pharmacology, such studies are an important part of clinical research. Generally a diagnostic procedure, although experimental, is intended to be of benefit to the patient upon whom it is performed. However in the development and evaluation of a new diagnostic test, values on a series of control subjects are generally needed. Where only blood and urine samples are obtained, this does not present great problems; the normal volunteers undergo essentially no risk and only the minimal discomfort of a venipuncture. The control material for tests involving biopsies are ordinarily obtained from autopsy material, however there is considerable current interest in utilizing tissue and organ culture to examine biopsy specimens functionally. To evaluate functional diagnosis in disease properly it is essential that similar material be obtained from

unaffected individuals. Hence volunteers may be asked to undergo skin, bone, intestinal and liver biopsies. In addition there are many diagnostic procedures which involve the injection or ingestion of drugs or dyes which can produce occasional adverse reactions. Since the risks in these two instances here are quite substantial and those taking the risk will not benefit medically, the complex tripartite evaluation scheme recommended for phase one trials ought to be applied. Unfortunately this direct and suitably monitored approach has often been circumvented by obtaining "control" data from those patients subjected to a particular procedure who do not turn out to have the disease in question. Such an approach leads to the temptation, perhaps unconscious, to test for a diagnostic possibility in a patient in whom the possibility is highly unlikely, simply to obtain additional data on a particular test or procedure. In this case risk-benefit analysis is applied in the more usual way discussed in part II of this paper, but in fact those asked to take the test are really not potential beneficiaries if the test is irrelevant. The best way to avoid this misapplication of a diagnostic test is to insist that the risk-benefit analysis be applied by the tripartite method.

Finally I would like to mention a disparity between riskers and beneficiaries which the National Commission may not consider as part of its charge, but which could reflect on our national morality. We are increasingly dependent on other countries for the development and evaluation of new drugs. We congratulate ourselves on avoiding the use

of thalidomide, but we could only know the risk because others took it. Clearly we should not take risks simply because investigation and review bodies in other countries are willing to do so. However we must also be careful not to use this willingness for our own benefit. On a recent visit to Africa I was concerned that foreign pharmaceutical firms might be using African patient populations to test new drugs with less regard for safety than they would have had in using their own nationals as subjects. To apply rigid criteria at home and tacitly approve less safe trials abroad is not morally defensible.

II. Risk-benefit analysis when the risks and the benefits are likely to accrue to the same individuals or groups.

This problem can be divided into two parts:

- A) those circumstances in which the risks or the benefits are small, but of sufficient substance to make an analysis worth considering and,
- b) those circumstances in which both the risks and benefits are large. The latter applies to the development and evaluation of therapy for serious illnesses for which current treatment is not adequate. The circumstance in which the risks are large and the potential benefits small is obviously one to be avoided. However as exemplified by the thalidomide disaster, and the experience with chloramphenicol the existence of excessive risks may not be appreciated until extensive trials have been conducted.

Investigators and review groups must be alert to this possibility so that no further studies will be conducted once this disparity between risk and

benefit known to exist. The situation in which the risks are small and the benefits large is simply a desirable extension of the second category.

A. Many trials in which both risks and benefits are small involve disparities between those who take the risks and those who will benefit but the approach may be different from that considered in part I. Research in clinical pharmacology often involves the evaluation of agents which are expected to bring definite but limited benefits to the subject and to other patients with similar disorders. Such agents may turn out not to be beneficial to many of the patients treated initially. For example, in the evaluation of a new analgesic designed to replace aspirin in patients who cannot tolerate aspirin, the new drug might be used in patients who can tolerate aspirin and therefore are best treated with the older established drug. Such use can be justified because the risk is small and transient, and the benefit to others appreciable. Similarly in the reevaluation of currently available drugs or particular uses of those drugs which are of questionable merit, the expectation may be that there will be little benefit to the patients in the trial. There would be a benefit to future patients and to society if it could be clearly shown that a particular use of that particular agent should be discontinued. Risk-benefit analysis in this situation usually does not present unsurmountable difficulties and does not require the complex tripartite evaluation discussed in Part I. The risks are usually well known for already established agents. If the

agents are to be used for relief of minor symptoms, low risk must be demonstrated and the benefits are usually such that both physicians and non-physicians can appreciate and evaluate them.

One serious problem in risk-benefit analysis for drugs of this type is in dealing with what might be termed the information-use gap. Information derived from a trial is rarely used optimally for several reasons: 1) It may be difficult or inappropriate to apply the information of the trial to the larger population at risk. Consider the television advertisement for a drug taken predominantly for headache, in which the huckster points out that in studies on "pain other than headache, doctors at a teaching hospital and major medical center found agent X to be superior". 2) Individual clinical trials can be assessed by appropriate statistical means and careful descriptions of the patient population can be presented, but only after the accumulation of a number of such trials and the analysis of many relevant patient and disease factors can one arrive at a consensus concerning the therapy of larger populations. The validity of this consensus cannot be tested by ordinary statistical means. It is a matter of weighing evidence which seems more judicial than scientific. Hence we find physicians telling about their clinical judgement and we are faced with the difficult problem of deciding which physician's judgement to accept. Perhaps some of the difficulty in this area would be resolved if those who are asked to weigh the evidence were trained not only as physicians and scientists but as lawyers and judges. The group which make such decisions, be they hospital pharmacy committees, state or federal purchasing agents

or the National Research Council Advisory Boards to the FDA might profit from more input by those familiar with judicial procedure. Scientific conclusions based on reproducibility, statistical validity and quality of the experimental design could be enhanced by the judicial assessment in the traditional terms of competence, relevance and materiality. 3) While such an approach might help us make a better assessment of therapeutic questions, it will not insure that new judgements, whatever their quality, are distributed appropriately. The availability of a careful assessment is not sufficient to close the information-use gap. After the risks and benefits of a particular therapy have been analyzed these must be presented so as to be understood by those who will use the therapy. The proportion of adverse reactions to a given drug which occur due to misinformation, misunderstanding or misuse by the physician or patient is generally much greater than the proportion of adverse reactions which occur because of unavoidable side effects during correct use of that drug. There is no absolute way of ensuring that the appropriate instructions will be carried out by physicians, patients or society. We have few groups which attempt to monitor the use and distribution of therapeutic agents and the findings of such groups may have little effect on the general use of an agent. This is a particularly severe problem in a capitalist system where profit has a powerful impact on the development and distribution of drugs. In the past beneficial drugs have not been marketed, because they were not profitable. The problem is compounded by the fact that physicians

use drugs in a highly independent manner. They regard, in some cases correctly, the advice and instructions in package inserts and other informational material as excessively and inappropriately restrictive. Thus the information-use gap may also occur because the official information has not kept pace with non-official information which nevertheless influences current use.

B. In considering the problem of assessing risks and benefits when both are large we need to take a fresh look at the relationship between patient and healer. Traditionally, the patient with a serious illness for which definitive therapy is not available is advised to seek out an outstanding physician (usually defined as one in whom others have much confidence), put themselves in the hands of that physician and do what they are told. This demonstration of faith is the fundamental tenet of the primitive healing arts, and remains the principle by which quackery, folk medicine and a wide variety of dubious cures still gain acceptance. On the other hand good healers, dedicated to their patients welfare and well-versed in scientific medicine also make extensive use of "faith in the physician" to carry out their therapy. Is it appropriate to ask a patient to accept this relationship and at the same time ask them to take part in an experiment ? In this setting it seems more appropriate to engage the patient as fully as possible as a partner in a scientific enterprise. To do this effectively may require a change in the attitude of society towards therapeutic research. Today sick patients are generally ill-prepared to take an active

role in decision making. I do not believe this is because sickness robs them of their judgement or because sick patients are intrinsically incapable of taking part in a decision concerning their own welfare. Rather it is because the tradition of faith in the physician is currently so powerful and pervasive. How common it is, after a long explanation of a patient consent form to hear the patient say: "I'll do what ever you think best, doc.". We must realize that the reason for this response may be that patients think that physicians expect it and are afraid to voice their underlying concerns. A substantial amount of education of both physicians and patients would be required to change this response. Nevertheless I believe that such education is necessary if we are to pursue clinical investigation actively in an era when new and powerful agents are continuously being made available, and require rapid induction.

Two additional problems arise when the risks are large and the potential benefits are great. One is the problem of whether, even with informed consent, individuals can be asked to take a substantial risk on the possibility that their health will improve. We allow individuals to take much greater risks for financial gain. How can a society which permits and sometimes even encourages death-defying stunts prevent a sick individual from taking a substantial risk in the hope of gaining health, or even stop a heroic martyr from taking a substantial risk in the hope of achieving better health for others? Fear of legal reprisals as a result of the malpractice explosion may have a powerful but inappropriate influence on

risk-benefit analysis in this situation. Better methods must be devised for dealing with the malpractice issue in clinical research.

III. Recommendations

Much of what follows has already been suggested in the discussion above. My recommendations for better procedures for risk-benefit analysis have been generated from experience in academic medicine in a hospital setting, as a clinical investigator and as an active participant on both sides of the institutional review procedure.

1. My major recommendation is that new procedures be developed for risk-benefit analysis of studies in which those taking the risks are different from those who benefit. As described above, I believe that there should be a tripartite review system for such studies. One group would have the appropriate expertise to analyze the risks and judge the propriety of the selection of volunteers to be certain that there is no element of coercion. The second group would consider the potential benefits and provide a disinterested evaluation of the likelihood that such benefits will eventually accrue. These two groups should then present their findings for actual risk-benefit analysis to a third group. This third group has the most difficult task. They must weight the personal risks taken by the volunteers against societal and personal benefits for others. It is clear that this group has a quasi-judicial function and should have the benefit of individuals trained in judicial and legal procedure. In carrying out this review, the risks of not doing the study should be carefully presented and considered.

The review system should have an appeal procedure embodied in it. It is possible that this could occur in several steps beginning at the local or institutional level and carrying through to the State and Federal levels. However it is implicit in a tripartite review system that the adjudicating group should not represent the institution at which the experiment on volunteers is to be conducted, but should have larger community representation.

2. For that large proportion of human investigation in which the patients asked to undertake a risk are also likely to benefit, because the therapy under study is designed for their disease, the present system of institutional review appears to be quite adequate. Such institutional review groups in hospitals, medical schools, and research institutes should have guidelines to help them determine whether in a particular instance risks and benefits are so separate that the more complex tripartite procedure might be appropriate. This problem can be identified easily when a specific phase I study of a new drug is being carried out in such an institution. The evaluation of a laboratory test in normals might come under further scrutiny, but only in those instances where there is some substantial risk involved. In the present composition of institutional review groups the regulation that representatives of the legal profession, the clergy and lay persons be included seems reasonable. At the moment it does not seem necessary to require that there be specific research advocates, that is individuals who will take it as their duty to point out the usefulness of

research, and the risks of not doing research. It may be that as review becomes more stringent and regulations become complex this function of institutional review will also have to be specified.

3. Probably the most important and difficult problem is that of improving the dissemination and application of therapeutic information and closing the information-use gap. No single approach will solve this problem.

A large number of changes ranging from reorganization of the distribution of medical care to improvement in public relations and the development of better instruments for informing physicians of new developments in therapeutics must be considered. The important first step is to recognize formally that this gap represents a major defect in our health system. Efforts to close it must be supported at all levels; local, State and Federal, from both the public and private sector and using a wide variety of techniques.

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INFORMED CONSENT

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NATURE AND DEFINITION OF INFORMED CONSENT
IN RESEARCH INVOLVING DECEPTION

Diana Baumrind, Ph.D.

January 28, 1976

Preface

My charge from the Commission is to discuss the nature and definition of informed consent in research involving deception. The discussion will not present a balanced and impartial view of all sides of this admittedly complex issue. Rather, I shall speak as a social scientist and to those issues which affect social scientists. Only in passing shall I be concerned with related ethical problems as they apply to biological and medical research.

For more than 20 years, I have been actively engaged in the practice of behavioral science research, and for more than half that time with the ethical issues which are raised whenever one does research with human subjects. I am known to hold a non-permissive position regarding the use of deception, and I shall speak as an advocate of that position. This I feel free to do in the expectation that Dr. Berkowitz, who has been asked to prepare a paper on the same subject, will argue in defense of research employing deception. Taken together, our two approaches should provide--at the least--one basis for a much needed dialogue.

By comparison with journal writing my style will be leisurely and to some extent repetitive. I shall risk redundancy for the sake of clarity and assume that the repetition of the same argument in different contexts is a necessary--if sometimes tiresome--corrective to possible misunderstandings. I shall use the male pronoun to stand for the human person because I find its avoidance in a philosophical paper too cumbersome.

Definition of Problem

Nature of Deception

Deception can be classified as nonintentional or intentional. *Nonintentional deception*, which includes absence of full disclosure, failure to inform and misunderstanding, cannot be entirely avoided. Full disclosure of everything that might affect a given subject's decision to participate is a worthy ideal

but not a real possibility. For example, in the case of young children and partially disabled adults the investigator must content himself with absence of dissent and with assent rather than consent. While the youngest child can communicate unwillingness to participate (dissent) and a somewhat older child can indicate willingness to participate but without full understanding of what will be required (assent), only the mature, reflective adult is truly capable of fully informed consent. All secondary analyses of data and some acceptable studies of public behavior commit "failure to inform," another form of nonintentional deception. And finally, since perfect communication is impossible to achieve there is probably always some degree of misunderstanding in the contract between researcher and subject. However regrettable, such misunderstanding is inevitable and as such is not a proper subject for this essay.

My concern in this paper is primarily with *intentional deception*. This includes the withholding of information to obtain participation, concealment in natural settings, manipulation in field experimentation, and deceptive instructions and manipulations in laboratory research.

The function of deception in social psychological experimentation is to construct relevant experimental controls by means of fictional environments. Fictional environments are designed to induce specific sets or expectancies in subjects by the creation of false social norms, by the use of misleading verbal instructions or by the presence of nonfunctional visual props including electrical and electronic gear (Seeman, 1969). The presumed function of concealment and withheld information is to cancel the effect of the observer on the phenomena being observed in the interest of objectivity--a goal that physicists have long since rejected on theoretical grounds (the Heisenberg principle).

Incidence of Use of Deception

The use of deception continues to be the rule rather than the exception in social psychological research today. No professional organization absolutely prohibits deceptive practices of the kind it associates with good research. The very thoughtful code of the American Anthropological Association (attached) (1973), does not prohibit inobtrusive surveillance; the extremely perfunctory code of the American Sociological Association (attached) (1968), contains no prohibitions at all nor does it require informed consent; and the extensive revised code of the American Psychological Association (1973), while advising against deceptive experimental practices, condones deception in all cases where the presumed benefit exceeds the presumed cost.

Several surveys document the use of intentional deception in social psychological research. Stricker (1967) surveyed the four major social-psychological journals published in 1964, (*Journal of Abnormal and Social Psychology* (JASP), *Journal of Personality* (JP), *Journal of Social Psychology* (JSP), and *Sociometry*). He found that some areas of research use deceptive strategies almost to the exclusion of nondeceptive strategies. Thus 81% of conformity studies and 72% of cognitive dissonance and balance studies involved deception, while such strategies rarely occurred in learning and attitude studies. Seeman (1969) analyzed the total published literature in the JP and the JASP from 1948-1963 for use of deceptive strategies. The mean figures combined for 1948 is 18.47% and for 1963, 38.17%. According to Menges (1973), also surveying JP and JASP, the percentage of studies reporting use of deception was 16% in 1961 and 38% in 1971. In 1973 the American Psychological Association (APA) revised its code of ethics giving careful consideration to the issues of informed consent and deceit in laboratory and field settings. If the revised code effectively reduced the incidence of deceptive practices we might expect to see a drop in

the incidence of published reports. I therefore examined the September 1974 issue of *Journal of Personality and Social Psychology* (JPSP), the official journal of the APA in the areas of personality and social psychology (which now replaces both JP and JSP), to see if a drop had indeed occurred. Of the 15 empirical studies reported, six used deceptive instructions in an intentional attempt to manipulate the subjects' set or to create false social norms. Thirteen months later (October 1975) I examined JPSP again for incidence of deception. The Table of Contents is included as *Table 1*. There were 20 empirical reports among the 22 papers. Of these, 13 employed deceit. Of the 13 that employed deceit, three were trivial instances (numbers 8, 12, and 17) in which (in my judgment) no harm, including loss of trust, could ensue either from the procedures themselves or from the disclosure of deceit in the debriefing. In number 8, subjects were told that their discussions were being videotaped when they were not; in number 12 that they would be "overcrowded" when they were not; and in number 17 that the lists of digits presented to them followed a certain order when in fact the order was random.

Ten studies employed nontrivial deceit which in my view involved clear violations of the ethical principles of the APA and/or could result in real psychological harm to the subjects. Of these 10, six made no mention of debriefing. Subjects, with two exceptions, were introductory psychology students or freshmen. Most of these studies dealt with such socially important themes as altruism or conformity and thus could be justified by the usual cost/benefit rationale. One of these ten (number 3) used deceptive instructions with 7-10 year old children to measure altruism; subjects were exposed to adult models behaving either altruistically or selfishly and were told that their winnings (preset, not genuine, scores) could be donated to poor children. Were debriefing used (none was mentioned) the children who had behaved selfishly would have

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suffered shame and guilt. At best, all subjects were left with false notions about their own performance and that of adult models. In two studies (numbers 11 and 23), experimenters delivered mild electric shocks as well as false instructions to undergraduate students with no debriefing by one (number 11). Another study (number 6) encouraged college students to cheat by using false instructions; no debriefing was mentioned. Data from two studies (numbers 1 and 2) investigating helping behavior were obtained by staging incidents with "victims" supposedly in need of assistance. In the 10 studies where nontrivial deceptive practices were used, informed consent was entirely precluded.

Nature and Definition of Informed Consent

Under the APA code of ethics and the present HEW guidelines, informed consent means the consent of a person (or his or her legally authorized representative) so situated as to be able to exercise free power of choice. Free power of choice, in turn, implies that choice be made on full and accurate information, including an accurate explanation of the procedures to be followed and a description of any attendant discomforts or risks reasonably to be expected. As usually stated, there are six basic elements of informed consent. In order to distinguish my use of the term *informed consent* from the usual literal interpretation, I will follow each element with a comment.

1. A fair and understandable explanation of the nature of the activity, its purpose, and the procedures to be followed, including identification of any procedures which are experimental.

The investigator should not be required to disclose to the subject the *purpose* of the experiment. The requirement that in effect the investigator share his hypotheses with subjects would invalidate most social science research. Obviously subjects' behavior will be affected by explicit knowledge of the investigator's hypotheses. It is deceitful for the investigator to misinform

the subject as to the purpose of the experiment, but not to explicitly withhold information. It is sufficient to indicate to the subject that such information cannot be shared during the initial briefing but will (or will not in some cases) be disclosed at the debriefing. Subjects should also be informed of the possibility that there will be secondary analyses of data. Some potential subjects may refuse to participate on the grounds that they will not be permitted to censor future use of the data. That is their right. However, having been informed and having consented, subjects should not be given the right to veto in primary or possible secondary analyses the investigator's use of his findings.

2. An understandable description of any attendant discomforts and risks reasonably to be expected.
3. An understandable description of any benefits reasonably to be expected.

Written statements of possible risks and benefits sound to subjects like threats and promises and are, I think, counterproductive. Where there is a possibility of attendant discomforts and risks, these should be discussed with the subject in a briefing interview so that wherever possible procedures can be accommodated to the subject's needs, or his inappropriate anxieties dispelled. While the investigator may promise specific rewards such as feedback information, referral or money, he can seldom determine in what ways the experience will be intrinsically beneficial or rewarding, although he can express his hopes that it will be.

4. An understandable disclosure of any appropriate alternative procedures that might be advantageous for the subject.

In behavioral research this alternative is not really open to the subject. Generally he must be assigned to a particular experimental or control group. It is essential, however, that the subject consent to the procedures to which he will be subjected.

5. An offer to answer any inquiries concerning the procedures.

The heart of informed consent is the right of the subject to be informed as to the actual nature of the experience which he is to undergo. It is to these procedures that the subject is consenting or withholding consent. Incomplete or inaccurate information here is tantamount to intentional deception.

6. An understanding that the person is free to withdraw his or her consent and to discontinue participation in the activity or the project at any time prior to its termination without prejudice to the subject.

Provided that fully informed consent has been obtained, the investigator should retain the right to encourage the subject to continue unless it becomes clear that the subject is being more than mildly inconvenienced. Certainly the experimenter should retain the right to withhold payment proportionate to the loss of the subject's services. Respect for the subject dictates that he has responsibilities as well as rights. While not constituting a legal contractual obligation on the part of the subject to continue or complete his service, acceptance of a prior fee *morally* obligates him to fulfill his part of the agreement. This obligation, of course, presumes that the subject has given his informed consent. And since the responsibility for assuring that consent is based on adequate information rests with the experimenter, any evidence that the subject did not anticipate the actual effects upon him suffices to relieve him of his contractual obligations--and this without financial or psychological penalty. But mere inconvenience should not relieve the subject of his moral obligation to continue and the experimenter should be able to exert tactful pressure towards that end, including withholding of payment for services not rendered.

Cost/Benefit Approach to Justification of the Use of Deception

Judging by their behavior, social scientists who use deceitful practices

do not regard such practices as immoral. Yet these same scientists would not condone the normative use of deceit in everyday personal relations. In the practice of their profession, however, these scientists use deceitful practices openly, publish their procedures without apology and indeed with prideful exhibition of ingenuity (e.g., Milgram, 1963), teach their students to copy their example and reward them when they do, and vigorously defend their procedures when attacked. Their justification is contained in the cost/benefit principle. The experience of being deceived or not fully informed is not in itself viewed as a cost. Provided the study's objective is of scientific or social interest and the methodology adequate, the cost/benefit principle can be, and is, in most instances, invoked to justify the use of deceit.

I will argue that the cost/benefit approach as generally applied serves to justify rather than inhibit the use of deceitful practices and misinformed consent. Moreover the costs to the subject and society are underestimated and the benefits to society are overestimated.

Inadequacy of Cost/Benefit Approach

As a basic principle of adjudication the cost/benefit justification of deceptive practices is inadequate. The cost/benefit justification of deceptive practices cannot be reconciled with Personalism or any other form of universalist metaethics, or with rule-utilitarianism provided that what is perceived as constituting the greatest general good prohibits the *justification* of lying and deceit. In accord with the deontological or universalist position the basic judgments of obligation are present as being given intuitively without recourse to consideration of what serves the common good. For deontologists such as Kant, the principle of justice or of truth or the value of life stands by itself without regard to any balance of good over evil for self, society, or the universe. For nontheistic deontologists, morality is, I suppose, equated with aesthetics, requiring of the moral individual a fine sensibility and intuition.

This is the view of Aristotle, when he states that the decision as to what determines the golden mean rests with perception. For theistic deontologists humankind is the bearer of "an alien dignity" rooted in the value God places on us. Personalism, or the idea that the life and integrity of the person remain of greater value than any object or function which the person may be called upon to serve, is central to both the Buddhist and Christian tradition. Nontheistic deontologists who agree with Wallwork (1975, p. 75) that "persons are of unconditional value" and that it is "the right of every person to an *equal* consideration of his *claims* in every situation, not just those codified into law or professional rules", must reject the costs/benefit analysis because it wrongly (from their perspective) subordinates basic human rights to benefits of whatever kind or value. According to rule-utilitarianism, an act is right if and only if the *principle* under which it falls is thought to produce at least as great a balance of good over evil as any available alternative. Unlike universalist principles, rule-utilitarian rules are culturally and situationally relative (a good thing, in my opinion). If deception is perceived as a fundamental principle governing an act then deception itself would have to be viewed as promoting the greatest general good. However, no ethical system does in fact condone lying and deception as a *principle* of action, although not all lies or deceptions are regarded as blameworthy, and many "white" lies are regarded as praiseworthy.

Telling the truth and keeping promises are regarded as obligatory in most systems of ethics for many compelling reasons. Perhaps the most compelling of all is the belief that the coherence of the universe cannot be maintained without contract. Contracts and promises provide the same security in the social world which invariant cause-and-effect relations provide in the physical world. Without invariant cause-and-effect relations in the physical universe,

goal-oriented behavior would be impossible. Imagine a situation in which turning a doorknob could release a stream of lemonade or trigger a gun or any number of other possibilities, as well as open a door. Only by acting in accord with agreed-upon rules, keeping promises, and avoiding deceit can human beings construct for themselves a coherent, consistent environment in which purposive behavior becomes possible. Thus, the long-range good that truth-telling promotes facilitates self-determination or authority over one's own person.

Rule-utilitarianism (to which I subscribe) unlike universalism does not pretend to establish the absolute validity of the ends sought. It accepts the possibility that deceptive research practices (or killing for that matter) can, under certain circumstances, be justified. The circumstances under which such justification is possible are those in which the *rule* requiring informed consent (or the not taking of human life) may be given a lower priority than the rule establishing freedom of scientific inquiry (or the rule prohibiting murder). In other words, if the values of science--to know and report--take precedence over the values that dictate concern for the person--integrity, reciprocity and justice--then should those two sets of values come into direct conflict, the values of science could be justified as an ethical basis for action. The crux of the issue, of course, has to do with establishing a hierarchy of values. This may be done by demonstrating that one rule or value (in a given culture at a given time) rather than another better facilitates the Good Life of one's own culture, humankind, or all sentient beings, depending on one's ultimate beneficiary. According to this view, if one believes (as I do) that values which dictate concern for the person take precedence over the values of science (in that factually the human values are more facilitative of the Good Life than the scientific ones), then a cost/benefit justification of deceitful practices

is proscribed.

By contrast with a rule-utilitarian, an act-utilitarian must calculate the costs and benefits of every situation without recourse to the guidance of overriding rules or principles, an approach which leads to unavoidable and unresolvable difficulties. Act-utilitarianism, for example, would require that in each instance the individual calculate anew whether or not to obey the laws against running a red light or stealing for personal gain. This concrete approach to ethical judgment occurs in the individual at an early period of development and is usually superseded by appeal to rule and principle as soon as the individual is capable of abstract thought. Act-utilitarianism would seem to restrict the moral sense to a rather primitive level. Moreover, act-utilitarianism is *presumptuous*. The actor presumes that he possesses insight superior to that of the distilled wisdom contained in the principle he disregards. Should a witness lie in a court of law to save a defendant he is sure is innocent? Joseph Fletcher, the Situation Ethicist, answers: "Yes, he should lie if he believes the defendant would otherwise be found guilty." (1966). The deontologist answers: "No, a lie is always wrong." The rule-utilitarian answers: "No. Provided that the court system functions justly, the common good is best served by truth-telling." The responsibility of the witness is to present his evidence convincingly. If he truly knows, why should his evidence not convince the court? To justify his willingness to lie, the witness would have to uphold the right of any witness to lie, provided that the witness felt sure in his own mind of the guilt or the innocence of the defendant. The principle which proscribes lying under oath is intended to preserve the common good by determining truth through consensual judgment rather than in accord with the strong conviction of any one man. Act-utilitarianism is *tied to the present*. Consider, for example, the guarantees of

the rights of the accused or the minority in the Bill of Rights. The exercise of these guarantees often creates a situation where the protection of the rights of an individual will violate the common good, e.g., the exercise of free speech to support racism. Act-utilitarians would have to reject the Bill of Rights in that situation, whereas rule-utilitarians would inquire as to whether the common good were benefited by universal adherence to the principle of free speech. The rule-utilitarian would evaluate the effect on the common good of violating that *principle* rather than apply cost/benefit analysis to this particular instance or act (verbal defense of racism). A rule-utilitarian would argue that if an objection to the content of a statement were used to justify a violation of free speech in this instance, then any objection to content could be used to restrict the right of a citizen to speak out, e.g., the right of a pacifist to speak out against the Vietnam War. Unlike the act-utilitarian, the rule-utilitarian would find the guarantees contained in the Bill of Rights consistent with his moral philosophy because these principles, if generalized, would benefit the common good. Act-utilitarianism is entirely *pragmatic*. Matters of conscience exercise different capacities and appeal to different motives in humankind than matters of practical judgment. Suppose that act A and act B result in exactly the same ratio of cost to benefit, but act A involves deceit and breaking a contract, while act B involves purchasing a cocktail dress rather than a pair of badly needed walking shoes. A consistent act-utilitarian would view acts A and B as both equally wrong if they both produced an identical score on the minus side. But from the deontological viewpoint, or that of rule-utilitarianism, act A must be regarded as more unethical than act B, otherwise there is no ethical question to be decided, only a practical one. Most present code of ethics, including the APA code and the HEW regulations, are written from an act-utilitarian metaethics. From either a universalist or rule-utilitarian position, the codes and their

metaethical justifications are inadequate.

In practice, present codes do not in point of fact regulate the activities of scientists so that they conform with generally held standards of ethical behavior; any rule can be violated merely by proclaiming that the benefits to humanity, or reducing inferential ambiguity, justify the costs to subjects. The argument for violations of subjects' rights on the basis of a cost/benefit analysis is well presented in the revised code of ethics of the APA.

The obligation to advance the understanding of significant aspects of human experience and behavior is especially likely to impinge upon well-recognized human rights. Significant research is likely to deal with variables and methods that touch upon sensitive human concerns. And if ambiguity in causal inference is to be reduced to a minimum-- an essential of good science--research must be designed in ways that, on occasion, may make the relationship between the psychologist and the human research participant fall short of commonly held ideals for human relationships. . . (1973, p. 8)

According to the APA code of ethics, when a conflict between scientific rigor and the rights of subjects arises, the experimenter's ethical obligations to the subjects may be superseded. To be specific, the following rights of the subject are recognized explicitly in the APA code but may be suspended in the interests of scientific rigor:

- a. The right of the subject to be involved in research only with his knowledge and informed consent (Principles 3 and 5).
- b. The right of the subject to be dealt with in an open and honest manner (Principles 4 and 8).
- c. The right of the subject to protection from physical and mental distress and loss of self-esteem (Principle 7).
- d. The right of the subject to a clear and fair contractual agreement (Principle 6).

Referring to the cost/benefit approach by which such violations are justified, the Code states:

Almost any psychological research with humans entails some choice as to the relative weights to be given to ethical ideals, some choice of one particular ethical consideration over others. For this reason, there are those who would call a halt to the whole endeavor, or who would erect barriers that would exclude research on many central psychological questions. But for psychologists, the decision not to do research is in itself a

matter of ethical concern since it is one of their obligations to use their research skills to extend knowledge for the sake of ultimate human betterment (1973, p. 7).

In making this judgment, the investigator needs to take account of the potential benefits likely to flow from the research in conjunction with the possible costs, including those to the research participants, that the research procedures entail. ... An analysis following this approach asks about any procedure, "Is it worth it, considering what is required of the research participant and other social costs, on the one hand, and the importance of the research, on the other?" Or, "do the net gains of doing the research outweigh the net gains of not doing it?" The decision may rule against doing the research, or it may affirm the investigator's positive obligation to proceed. Such an analysis is also useful in making choices between alternative ways of doing research. For example, "Are the costs to research participants greater or less if they are informed or not informed about certain aspects of the research in advance?" "What will be the effect of these two alternatives on potential gains from the research?" (1973, p. 11)

The revised Code assumes moral dilemmas are inevitable in the research endeavor; but the function of a system of moral philosophy is precisely to avoid such dilemmas. In point of fact, the use of a cost/benefit analysis serves to legitimate the loophole known as the "moral dilemma," that is, the situation in which the actor believes that he is forced to choose between *equally* culpable alternatives. But it is a person's duty insofar as possible to avoid provoking situations which create conflicts of obligation, since such conflicts by definition result in harm to some. Act-utilitarianism presented as a cost/benefit analysis readily lends itself to the "moral dilemma" loophole, whereas rule-teleology or rule-deontology do not.

Application of Cost/Benefit Approach

If a cost/benefit approach is adopted, then the costs and benefits must both accrue to the subject. In medicine the cost/benefit analysis is a weighing of the likely benefits to the patient of a proposed plan of treatment versus the probable costs (risks) to the patient--financial, physical and emotional--of that form of treatment. Thus a physician may present a woman who has a diagnosis of breast cancer with alternative treatments for her consideration, including chemotherapy, lumpectomy and radical mastectomy.

It is questionable whether the physician has the right to determine for the patient the balance of risk over benefit of such alternative treatment plans. It is certain, however, that the physician is not morally privileged to pass judgment concerning the balance of risk to the patient versus the benefit to humankind by using the patient as a medical guinea pig to test these alternative procedures. If she is to risk her personal welfare for the benefit of humankind the patient must, without qualification, have access to all available information concerning the effects of treatment in order that she, not the physician, may make that decision knowledgeably. The investigator who withholds information in effect imposes his perspective upon the subject about what is good for humankind, thereby repudiating the subject's right to his or her own informed perspective.

Most experimentation with human subjects places them "at risk" in the sense that they are treated as passive things to be acted upon, means toward an end they cannot fully understand. An individual may choose to incur some degree of risk, inconvenience, or pain by becoming an experimental subject. To accept these risks knowingly for the sake of others may be an act of charitable concern or an expression of commitment to the community. By agreeing to be a subject, a person to some extent relinquishes his sovereign will. When the subject accepts the research objectives and freely becomes a participant, he is rewarded by self-affirmation and social approval, much as is the scientist-participant. By serving an ideal such as progress, knowledge or human welfare, the subject and researcher accrue merit and a justified sense of self-enhancement. But a subject whose consent is obtained by deceitful and fraudulent means cannot recover his sovereign will. He remains instead a passive and obedient object for the experimenter to manipulate and is thus diminished rather than enhanced by his participation. Common law protects

individual freedom by proscribing manipulation of the psychological self. Possible benefits to mankind cannot justify legally (or morally) any exception to the requirement of full and frank disclosure to *each person* of all facts, probabilities and beliefs which a reasonable person might expect to consider before giving his or her consent. (See Mishkin's citation, 1975, p. 2, of Halushka vs. University of Saskatchewan, 1965).

Analysis of Costs of Deception

The costs of deception have been greatly underestimated. These costs are ethical, psychological, scientific and societal. If harm is defined as death or permanent mental or physical disability, then, with rare exceptions, harm to the subject will not result from behavioral science research. The effects, harmful and beneficial, are more subtle in behavioral science research than in medical research. The costs and benefits to the subject and to society are in the realms of feelings, cognitions and values rather than in physical and material realms.

I advocate the position that to intentionally deceive subjects or to obtain their consent fraudulently is to place them "at risk" even if they do not, as a result, experience additional stress or permanent harm.

It is important to note that all the provisions of the DHEW and APA codes (including the right to informed consent) apply only after a subject has been determined to be at risk. Only after probable risk has been established must the investigator determine that "the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks" (Federal Register, 1974). It seems evident to me that the substantive rights of subjects should be guarded by the DHEW regulations

whether or not additional harm from the violation of these rights can be demonstrated. If there is objection to guaranteeing the rights of subjects in addition to their welfare, then I would argue that psychological invasion is itself injurious to the subject's welfare. I agree with Mishkin (1975, p.2) that the law is moving "toward a model which protects against the invasion or manipulation of a person's *psychological self*."

Inherent in this broadened perspective on legal liability in behavioral research is an increased sensitivity on the part of community leaders to the ethical problems raised in abusing a fiduciary relationship. To the extent that special privileges are accorded professionals and academics as an extension of public confidence in their protective functions, a fiduciary relationship may be said to exist between this segment of the community and the rest. That is, the professional segment of the community in its relationship with the rest may be viewed as trustees of the values inherent in its activities--such values as integrity, compassion and trustworthiness.

1. Ethical Costs of Deception. Any moral system which places preeminent value on humankind's reason and moral autonomy will allow few exceptions to the rule of informed consent. By moral autonomy is meant the right and obligation of each mature, healthy human being to assume personal responsibility for his actions. In accord with this view, the right of the subject to choose freely to participate in research is inviolable, not to be abridged by the investigator, although it may be waived by the subject. Doing research on people without their knowledge and informed consent is unethical under all circumstances. Principle 3 of the APA Code of Ethics reads:

Ethical practice requires the investigator to inform the participant of all features of the research that reasonably might be expected to influence willingness to participate, and to explain all other aspects of the research about which the participant inquires. (But then the

qualification:) The decision to limit this freedom increases the investigator's responsibility to protect the participant's dignity and welfare (1973, p. 42).

Contained within each of these principles concerned with informed consent is a qualification which permits the principle to be violated although it is explicitly stated that ethically acceptable research requires establishment of a clear and fair agreement between the investigator and the research participant and that the investigator is obliged to honor all promises and commitments included in that agreement. But a subject who has been deceived as to the nature of his agreement cannot enter into a clear and fair agreement in the first place. These qualifications are not wrong because the subject may be exposed to suffering, but inequitable because a subject deprived of the right to informed consent has thereby been deprived of his right to decide freely and rationally how he wishes to invest his time and person. He has also been unjustly tricked into thinking his consent was informed when it was not. If as a result of the experimental manipulations the subject has in addition been entrapped into revealing to himself and others undesirable characteristics such as destructive obedience, dishonesty or sadism, he has truly relinquished more than he bargained for. Fundamental moral principles of reciprocity and justice are violated when the behavioral scientist acts to deceive or diminish those whose extension of trust is based on the expectation that persons to whom trust is accorded will be trustworthy in return.

The experimenter by his deceitful actions violates the implicit social contract which binds experimenter and subject in which the subject assumes that the experimenter is both knowledgeable and trustworthy and that his code of ethics does not contain a "buyer beware" clause. Neither does the subject assume that the accumulation of knowledge has priority in the experimenter's hierarchy of values over decent treatment of the subject-participant. In

view of the special vulnerability, both personal and moral, which the subject invites by suspending disbelief and extending trust, the experimenter should agree to abide by a code of professional ethics more stringent, not less stringent, than his personal code.

As Kelman (1967) notes, most of us in our interhuman relationships do not expose other to lies, deliberately mislead them about the purposes of an interaction, make promises we intend to disregard or in other ways violate the respect to which all fellow humans are entitled. Yet we do so and feel justified in so doing in the experimenter-subject relationship. I have argued here that we ought to abide by a more, not less, stringent code of ethics in professional situations. Instead we *justify* our treatment of subjects solely as objects on the basis of our professional role. Thus we legitimize as well as commit ethical violations. The legitimization itself has harmful effects: it relieves the investigator of culpability and of the responsibility for devising non-deceitful alternatives or making reparation; it promotes false values that worthy ends such as the pursuit of truth justify unworthy means such as the use of deceit.

2. Psychological Costs of Deception. Deceitful practices are most costly to the person when they have the following characteristics:

a) The implicit or explicit contract between two persons is violated by one party (aggressor) without the consent of the other (victim) to the benefit of the aggressor and the detriment of the victim.

b) The effect on the victim is to: (1) impair his ability to endow his activities and relationships with meaning, (2) reduce trust in legitimate authority, (3) raise questions about regularity in cause and effect relations, (4) reduce respect for a previously valued activity such a science, (5) negatively affect the individual's ability to trust his own judgment, or (6) impair the individual's sense of self-esteem and personal integrity.

c) The aggressor is respected by the victim and therefore could serve as a model.

The effects upon subjects which I judge to be most harmful are those which result in cynicism, anomie, and hopelessness. In my view, the most injurious consequence that can befall a person is to lose faith in the possibility of constructing for himself a meaningful life. Any experience which diminishes that faith inflicts suffering and possible harm. College students, who are the most frequently used subject pool, are particularly susceptible to conditions that produce an experience of anomie.

I want now to illustrate the way in which I believe deceit and manipulation place subjects at psychological risk. My former secretary, Paula Lozar, described an incident which illustrates the way in which deception in an experimental setting can contribute to a young person's feeling of anomie as loss of faith in the meaningfulness of life.

When I was 18, a sophomore in college, a psychologist from a nearby clinic came to my dormitory one evening and explained that he was looking for subjects for an experiment which involved simply telling stories about pictures which would be shown them. This sounded interesting, so I signed up. At the interview the same psychologist introduced me to a girl a few years my senior, who stayed bland and noncommittal throughout the time she interviewed me. She showed me a few pictures, and since they were extremely uninteresting I felt that the stories I was making up must be very poor. But she stopped at that point and told me that I was doing very well. I was gratified and said something to that effect before we went on to the rest of the pictures. Then I filled out a form about my reactions to the interview, the experimenter, etc., and she took it and left. After being alone for a few minutes, I looked around the office and noticed a list of the last names of subjects, with "favorable" and "unfavorable" written alternately after each one. Shortly thereafter the male psychologist returned and said that, as I had guessed, what the interviewer had said had nothing to do with my performance. They were testing the effects of praise and dispraise on creative production, and he said so far they had discovered that dispraise had negative effects and praise seemed to have none at all. Since I expressed interest, he promised that the subjects would be given full results when they were tabulated. (But we never heard from him.)

My reaction to the experiment at the time was mixed. I assumed that the deception was necessary to get the proper reaction from me, and that

since I had behaved unsuspiciously the results of the experiment were valid. However, I was embarrassed at having been manipulated into feeling pride at a non-achievement and gratification at praise I didn't deserve. . . . Since in my early years in school I had alternated between being praised for doing well and being damned for doing too well, I had always been a poor judge of my own achievements and had no internal standards for evaluating my performance--although I knew I was very intelligent and felt that some sort of moral flaw kept me from doing as well as I might. At the time, I was attending a second-rate college and felt (rightly) that my grades had nothing to do with how well I was really doing relative to my ability. This experiment confirmed my conviction that standards were completely arbitrary. Furthermore, for several years I had followed a pattern of achievement in which I would go along for quite a while doing well in classes, interpersonal relations, etc. Then I would have a moment of hubris in which I was more self-confident or egotistical than it behooved me to be in that situation. At this point someone would cut me down to size; I would be totally devastated, and it would take me a long time to work myself up to my previous level of performance. The experiment had, in a lesser degree, the same effect upon me, and it . . . confirmed me in this pattern because the devastating blow was struck by a psychologist, whose competence to judge behavior I had never doubted before. . . . It is not a matter of "belief" but of fact that I found the experience devastating. I told literally no one about it for eight years because of a vague feeling of shame over having let myself be tricked and duped. It was only when I realized that I was not peculiar but had, on the contrary, had a *typical* experience that I first recounted it publicly. . . .

At the time of the experiment, I had arrived at a position *common* to young adults who have lost confidence in external standards, either ideals or authorities, as a guide to how to live, and was in the process of formulating my own standards. As a result of my early lack of self-confidence and inconsistent school experiences, my task had been laborious and not entirely successful. . . . The experiment confirmed me in my lack of success. I had been led into a situation where I was explicitly told to disregard my own interpretation of what was going on and made to perceive it another way, and then eventually told that *both* ways I had perceived it were wrong. . . . The result was to further convince me that my perceptions were useless as a guide for action, and that, since the only person I felt I could trust--myself--was not trustworthy, I had no way of judging how to act and hence it was better not to act at all. . . .

I was harmed in an area of my thinking which was central to my personal development at that time. To me, and to most of my classmates, the task of setting one's own standards, of formulating guides to living. . . . was one of the most important tasks we faced. This had to do with . . . one's ability to *give* meaning to one's life. I rather suspect that many of us who volunteered for the experiment were hoping to learn something about ourselves that would help us to gauge our own strengths and weaknesses, and formulate rules for living that took them into account. Something of the sort was, I know, in the back of my own mind. When, instead, I learned that I did not have any trustworthy way of knowing myself--or anything else--and hence could have no confidence in any lifestyle I formed on the basis of my knowledge, I was not only disappointed, but felt that I had somehow been cheated into learning, not what I needed to learn, but something which stymied my very efforts to learn.¹

¹Lozar, P. Personal communication, 1972.

Ms. Lozar thus describes the serious effects she felt this deception had on her, and they are precisely the kinds of effects which I designated earlier as "most costly." Yet many investigators regard none of these effects as real, demonstrable or serious. Whose criteria concerning psychological costs are to be adopted?

3. Scientific Costs of Deception. The scientific costs of deception in research are considerable. These costs include: a) exhausting the pool of naive subjects, and b) jeopardizing community support for the research enterprise. If these costs are real it will become increasingly difficult to do valid research; we may be damaging chances for others to work in the same locations or on the same problems. This harm may be irreversible.

a) *Exhausting the pool of naive subjects.* In the experimental situation, the investigator must assume that subjects accept the reality of the situation as defined by the experimenter, or that if subjects fail to do so that the investigator knows this. But there is increasing reason to doubt that subjects are indeed naive. As a result of widespread use of deception, psychologists are suspected of being tricksters. Suspicious subjects may respond by role-playing the part they think the experimenter expects, doing what they think the experimenter wants them to do (Orne, 1962) or pretending to be naive.

Wahl (1972) has summarized the growing body of evidence that deception in psychological research is not effective and subjects are not naive. Wahl documents his assertions that it is neither theoretically nor practically defensible to assure subject naiveté by deception, and that experimental realism obtained through situational deception is not necessarily more successful than the realism of deception-free situations. Moreover, Wahl concludes from his review that experimenters cannot distinguish subjects for whom

the deception promotes experimental realism from subjects who merely pretend to be fooled. If the widespread use of deceit has decreased the likelihood that subjects will be naive, as Wahl's survey suggests, such practices are obviously counterproductive. If the sample to be used in any given study is biased already (such as jaded lower-division psychology students), then the argument that informed consent may be dispensed with in order to assure an unbiased sample becomes unconvincing. It is an essential part of the teaching responsibility of professors to feed research findings back to the student subject pool through lectures and articles. This cumulative knowledge is then passed on to successive generations of students. Undergraduate psychology students, the most frequently sampled of all populations, are of necessity sophisticated. We must assume that their knowledge interacts with experimental conditions to produce results which may not be replicable in the general population.

Any population subject to behavioral science research will be similarly affected. Thus Brody (1967) found that almost all members of a delinquent sample chose delayed reward under experimental conditions while a normal sample selected both delayed and immediate reward under the same conditions. The delinquent sample findings were contrary to predictions and led to further probings which revealed that similar research had been recently conducted in that institution so that the subjects were not naive.

b) Jeopardizing community support for the research enterprise. The power of the scientific community is conferred by the larger community. Social support for behavioral science research may be jeopardized by investigator's encapsulation within parochial values if these values conflict with more universal principles of moral judgement and moral conduct. The very existence of the Commission suggests that the use of unethical research practices has

jeopardized community support. Congress no longer appears to trust the professional associations to police themselves. We really do not know the public's attitude today towards the scientific enterprise. We should, so that these attitudes can be considered when formulating ethical codes, so that investigators will be more aware of their responsibility to constituents and supporters, and thus to the community at large.

4. Societal Costs of Deception. Social science research through its methods and substantive findings has widespread political and social effects.

It can be argued that by its very nature social science research is a political act. In the research endeavor, certain participants (those in charge), are in power with control while other participants (the subjects), are defined as "objects" of assessment. Frequently these "objects" are exposed to the investigator's values in a highly coercive situation. For example, most investigators embrace an ideology of individualism which knowingly or unknowingly they impose on subjects. What the subject may have thought of as cooperation may be labelled destructive obedience as in the Milgram situation, or what he may have thought of as social cooperation is labelled as external locus of control (e.g., by Rotter). The use of fraud and deceit while the subject is in a heightened state of suggestibility, as he is when truly naive, should be thought of as increasing the risk that the subject will internalize at least temporarily the investigator's values, even if these are antithetical to his own. The investigator may be convinced of the rectitude of his values (as Milgram is) but does he have the right to *impose* his values on subjects (as Milgram does)?

The scientific justification for using deception is to assure subject naiveté. But it is the naive subject who is disproportionately placed "at risk" by the use of deceit and fraud because he risks disillusion and brainwashing. The sophisticated subject, already suspicious, is merely confirmed

in his cynicism by deceitful practices. But to the extent that subjects are sophisticated, the experimental deception has failed to increase the scientific or social benefit of the experiment. Thus it would appear that deception is least justified ethically when it is most successful.

If praxis in the laboratory or natural setting cannot be isolated from praxis in daily life, the implications are far-reaching. If subjects learn they cannot trust those whom by social contract are designated trustworthy and whom they need to trust to avoid feeling alienated from society, then the damage done to the subjects and to society by the enacted values of researchers is very real.

Subjects are given objective reasons to distrust authorities in whom they should have confidence, and apparently they are affected by this experience.

For example:

Fillenbaum (1966) found that deception led to increased suspiciousness (even though subjects tended not to act on their suspicions), and Keisner (1971) found that deceived and debriefed subjects were "less inclined to trust experimenters to tell the truth," (p. 7). Other authors (Silverman, Shulman, and Wiesenhal, 1970; Fine & Lindskold, 1971) have noted that deception decreases compliance with demand characteristics and increases negativistic behavior. (James M. Wahl, 1972, p. 12)

Ring, Wallston and Corey (1970), in their follow-up interview exploring subjective reactions to a Milgram-type obedience experiment reported that many subjects stated that they were experiencing difficulty in trusting adult authorities. In most of these studies mild and non-threatening deceptions were used, so that one speculates about the possible unknown lasting corruption of trust resulting from more severe deceptions.

Truth-telling and promise-keeping serve the function in social relations that physical laws do in the natural world; these practices promote order and regularity in social relations, without which intentional actions would be very nearly impossible. By acting in accord with agreed-upon rules, keeping promises, acting honorably, following the rules of a game, human beings construct for

themselves a coherent, consistent environment in which purposive behavior becomes possible. Animals, other than man, have limited capacity for manipulations and feints. Humankind may unnecessarily complicate their quest for survival by employing deceit and manipulation as an accepted part of a valued activity.

I believe that it is good for people to place a value on the activities of behavioral scientists and on the values inherent in scientific activity. The disciplined exercise of intelligence in science or art is of value in itself and this value does not depend upon the betterment of the material aspects of life to which it rightfully leads. If the rule which justifies scientific experimentation is "You shall know the truth and the truth shall set you free," then that rule applies also in the conduct of science. The use of the pursuit of truth to justify deceit risks the probable effect of undermining confidence in the scientific enterprise and in the credibility of those who engage in it.

Analysis of Benefits of Deception

There can be societal benefits to the use of deception only if there are probable scientific benefits associated with its use that are obtainable in no other way. The basic rationale for the experimental method is contained in the revised code of ethics of the APA as part of its justification of a cost/benefit analysis.

Not only do ethical questions follow from the psychologist's pursuit of important independent and dependent variables but the methods that are adequate to make inferences as unambiguous as possible tend to be the ones that raise ethical difficulties. Many psychologists believe (though some question this) that to obtain valid and generalizable data, it is often essential that the research participants be naive. The requirements of research may thus seem to demand that the participants be unaware of the fact that they are being studied or of the hypotheses under investigation. Or deception may appear to be necessary if a psychological reality is to be created under experimental conditions that permit valid inference (1973, pp. 8-9).

Many scientists are calling into question the implications contained

in the above statement, (e.g., Chein [1972], Guttentag [1971], Harré and Secord [1972], Kelman [1966], and Orne [1962]). Schultz concludes in his critical examination of the history of human experimentation

... that psychology's image of the human subject as a stimulus-response machine is inadequate and that many studies are based on data supplied by subjects who are neither randomly selected nor assigned, nor representative of the general population, nor naive, and who are suspicious and distrustful of psychological research and researchers (1969, p. 214).

As a number of critics including Brandt, Guttentag, Mixon and myself have pointed out, the ecological validity of studies widely acclaimed for their scientific merit is so questionable as to raise serious objections concerning the benefit to society of generalizations based on these findings. A case in point is the Milgram study (1963):

The following is Milgram's abstract of his experiment:

This article describes a procedure for the study of destructive obedience in the laboratory. It consists of ordering a naive S to administer increasingly more severe punishment to a victim in the context of a learning experiment. Punishment is administered by means of a shock generator with 30 graded switches ranging from Slight Shock to Danger: Severe Shock. The victim is a confederate of E. The primary dependent variable is the maximum shock the S is willing to administer before he refuses to continue further. 26 Ss obeyed the experimental commands fully, and administered the highest shock on the generator. 14 Ss broke off the experiment at some point after the victim protested and refused to provide further answers. The procedure created extreme levels of nervous tension in some Ss. Profuse sweating, trembling, and stuttering were typical expressions of this emotional disturbance. One unexpected sign of tension--yet to be explained--was the regular occurrence of nervous laughter, which in some Ss developed into uncontrollable seizures. The variety of interesting behavioral dynamics observed in the experiment, the reality of the situation for the S, and the possibility of parametric variation within the framework of the procedure, point to the fruitfulness of further study (p. 371).

The fundamental question Milgram asks is "how does a man behave when he is told by a legitimate authority to act against a third individual?" (p. 851) Milgram generalizes his findings to apply to the actions of men in combat and guards in Nazi concentration camps. According to Milgram, "within the general framework of the psychological experiment obedience varied enormously from one condition to the next." (p. 851) Well, then, to what social conditions does

the laboratory condition reported (1963) have generality? The experimenter's directive to dangerously shock the victim is, on the face of it, inappropriate in a psychological setting, and perhaps bizarre. A specialist in the science of psychology is expected to display compassion and personal integrity, so that such an order "to act harshly and inhumanely against another man" (p. 852) is incongruous. There is nothing incongruous about that order in a setting such as military combat. An officer and a psychologist are quite different kinds of authorities. The superior officer is an authority in the sense that he can require and receive submission and is authorized by the state to command obedience and is given the power to control and punish subordinates for disobedience. A psychologist relating to a subject or client has the authority of a specialist in a given field whose statements in that area can reasonably be considered authoritative. His area of legitimate authority rests not on power to punish, but upon trust extended by the subject or patient and based on the psychologist's claim to wisdom, knowledge, and professional integrity. Both the enlistee and the subject assume an integral aboveboard relationship not based on personal gain in the narrow sense. But the similarity cannot be pushed much further provided that normal conditions prevail. The military officer who orders enlisted men to fire upon the enemy engenders in their minds a very different kind of conflict, if any conflict at all, than the conflict engendered by the psychologist when pressing the subject to severely shock the victim. The officer's order to fire upon the enemy is patently appropriate to the situation. If the officer ordered the enlisted man to fire upon comrades further up front in order to prod them forward in the common cause, that condition might indeed be likened to the experimental condition. There are situations like that for which Milgram's condition is valid, but they are not a part of normal social life as he suggests.

The dissonant demands made upon the subject in a laboratory setting might reasonably produce a sense of unreality and absurdity quite different from that experienced in any normal setting. While in a state of confusion brought about by this unique juxtaposition of cues, the subject is urged to act. Disobedience in this setting is as likely to reflect flight and indecision, or fight against authority, as a moral decision to refrain from hurtful action. Obedience is as likely to reflect a sense of fair play and employee loyalty as a lack of moral sense or weakness of character.

Mixon (1974) repeated Milgram's experiment in an effort to understand the contexts in which subjects obey and disobey.

. . . I found that when it became perfectly clear that the experimenter believed the "victim" was being seriously harmed all actors indicated defiance to experimental commands (Mixon, 1972). Briefly summarized, the All and None analysis suggests that people will obey seemingly inhumane experimental commands so long as there is no good reason to think experimental safeguards have broken down; people will defy seemingly inhumane experimental commands when it becomes clear that safeguards have broken down--when consequences may indeed be what they appear to be. When the experimental situation is confusing and mystifying as in Milgram's study, some people will obey and some defy experimental commands. (pps. 80-81)

Another explanation for the behavior of Milgram's obedient subjects is offered by Brandt.

Had Milgram considered himself as just another human being from whose behavior something can be learned about human behavior in general. . . he would have known that human beings can inflict suffering on other human beings, if they can rationalize their behavior. Self-examination could have told him so. (1971, p. 237)

When "subjects" are viewed by the experimenter in the dictionary meaning of the word, the authoritarian relationship can lead the experimenter to consider their behavior as "obedience." The implicit assumption is then made that *experimental psychologists differ from human experimental subjects to such an extent that similar overt behavior by the two groups cannot be assumed to result from similar covert causes* (motivations, needs, drives, etc.). This distinction between experimenters and subjects is evidenced by explaining similar behavior of the two in terms of dissimilar motivations. In Milgram's experiments both experimenter and subjects inflict pain on others. This infliction of pain on others is explained by Milgram as "obedience" when done by the subjects and as "examining situations in which the end is unknown" (1964b, p. 848) when done by the experimenter. (1971, p. 239)

In the Milgram experiment, the presence of the experimenter sanctioned

aggressive behavior on the part of the subject as Milgram's authority sanctioned the aggressive behavior of the experimenter and stooge.

Holland (1968), focusing his analysis on the deception manipulation, demonstrated with three experiments that a high percentage of Milgram's subjects probably detected the deception without Milgram's knowledge. Mixon (1972) argues that subjects may always be expected to suppose the existence of at least minimal precautions safeguarding the physical well-being of subjects, and that therefore the judgment that Milgram's obedient subjects behaved in a "shockingly immoral" fashion is quite gratuitous. The generalization of Milgram's findings to real life conditions--people will comply with an imperative whose effects they believe harmful to another non-threatening individual--is not as self-evident as many social psychologists seem to think.

I have questioned in some detail the scientific validity of Milgram's research because it is frequently cited as an example of using deception in which the scientific and social benefits are very great, even if they do not outweigh the costs to the subject. I have tried to show, however, that Milgram's procedures are not only ethically unjustifiable--whatever their presumed benefits--but also, from a strictly scientific point of view, inconclusive. Far from studying real life in the laboratory as he thought he was, Milgram in fact may have constructed a set of conditions so internally inconsistent that they *could not* occur in real life.

Many critics of the experimental method believe that laboratory studies typically preclude ecological validity. Thus Guttentag (1971) states

Although the classical model holds sway in psychology, there are a number of issues which continue to be raised about it and the logic of statistical inference with which it is associated. . . The independence of the subject and the experimenter is difficult to assume in much research. . . Another problem is the experimenter's assumption of an essential independence and neutrality of each subject unit; i.e., that human beings are interchangeable. . . Although the logic of

experimentation and of statistical inference requires the assumption, one may still question whether it is a tenable one
. . . even when the individuals from such populations are randomly assigned to experimental conditions; given that people live within social systems, there is no logical guarantee that some condition which affects all subjects uniformly, a condition unknown to the experimenter, is not interacting with the experimental variables to produce a particular set of findings (1971, pp. 80-81).

The rigorous controls which characterize the laboratory setting may prevent generalizations to the free social environment. The extent to which one may generalize from behavior observed in the laboratory to the life situation is negatively related to the change which containment and control produce in that behavior. While the subject is familiar with the individuals, setting, and stimuli in his natural environment, he is unfamiliar with those in the laboratory setting. His reactions to the novel, or to the familiar in incongruous settings will affect his behavior. The power relations are qualitatively different in the experimental setting. There, the experimenter is the controlling party and the subject is an object of control. The two are in an authoritarian relationship in a setting unfamiliar to the subject.

We know that ambiguity of causal inference is an inherent part of research in the social sciences. Yet we continue to act as if the perfect experiment is just around the corner and, but for our ethical scruples, we would readily reach that scientific millenium.

Nature and Definition of Informed Consent in Field Research

As skepticism has increased concerning the veridicality of subjects' behaviors in experimental studies, particularly in personality and social psychology, the use of naturalistic experimentation and naturalistic observation has grown. In *naturalistic experimentation* the investigator intervenes to affect the normal behavior of the person observed while in *naturalistic observation* he does not. In either instance participants may be unaware that they are

participating in research at the time the data are collected. That research activity is occurring is concealed in a number of ways, including covert observation and recording of public behavior, obtaining information from third parties, disguised field experimentation and covert manipulations.

Silverman (1975) provides us with the following synopsis of prototypic naturalistic experiments:

1. Persons selected at random are phoned. The caller pretends that he has reached a wrong number, using his last piece of change, and that his car is disabled on a highway. The party is requested to phone the caller's garage and ask them to come for him. The garage number is actually the caller's phone and another experimenter, standing by, pretends to take the message (Gaertner & Bickman, 1972).

2. Automobiles, parked on streets, look as if they were abandoned. (License plates are removed and hoods are raised.) Experimenters hide in nearby buildings and film people who have any contact with the cars (Zimbardo, 1969).

3. People sitting alone on park benches are asked to be interviewed by an experimenter who gives the name of a fictitious survey research organization that he claims to represent. At the beginning of the interview, the experimenter asks a person sitting nearby, who is actually a confederate, if he wouldn't mind answering the questions at the same time. The confederate responds with opinions that are clearly opposite those of the subject and makes demeaning remarks about the subject's answers; for example, "that's ridiculous"; "that's just the sort of thing you'd expect to hear in this park" (Abelson & Miller, 1967).

4. The experimenter comes to a home, says that he has misplaced the address of a friend who lives nearby, and asks to use the phone. If the party admits him, he pretends to make the call (Milgram, 1970).

5. A female and a confederate experimenter visit shoe stores at times when there are more customers than salesmen. One of them is wearing a shoe with a broken heel. She rejects whatever the salesman shows her. The confederate, posing as a friend of the customer, surreptitiously takes notes on the salesman's behavior (Schaps, 1972).

6. Housewives are phoned. The caller names a fictitious consumers' group that he claims to represent and interviews them about the soap products they use for a report in a "public service publication," which is also given a fictitious name. Several days later the experimenter calls again and asks if the housewives would allow five or six men into their homes to "enumerate and classify" all of their household products for another report in the same publication. If the party agrees, the caller says he is just collecting names of willing people at present and that she will be contacted if it is decided to use her in the survey. No one is contacted again (Freedman & Fraser, 1966).

7. A person walking with a cane pretends to collapse in a subway car. "Stage blood" trickles from his mouth. If someone approaches the victim, he allows the party to help him to his feet. If no one approaches before the train slows to a stop, another experimenter, posing as a passenger, pretends to do so and both leave the train (Piliavin & Piliavin, 1972).

8. One experimenter takes a seat next to someone sitting alone in a subway car. Another experimenter approaches the person sitting next to the first experimenter and asks if the train is going downtown. The first experimenter intercedes before the party has a chance to answer and gives the wrong information. The second experimenter thanks him and takes a seat nearby (Allen, 1972).

9. Letters, stamped and addressed to fictitious organizations at the same post office box number, are dropped in various locations, as if they were lost on the way to being mailed. Some are placed under automobile windshield wipers with a penciled note saying "found near the car." (For one study with this procedure, the permission of the Post Office Department was obtained to use the names of fictitious organizations; Milgram, 1969.)

10. Experimenters, walking singly or in pairs, ask politely for either 10¢ or 20¢ from passersby, sometimes offering an explanation for why they need the money (Latané, 1970). (p. 765)

Both Nash's comment on that paper (Nash, 1975) and Mishkin's later paper (1975) expound the concept of injury to include protection of the psychological self. These papers point out that case law now includes deceit, invasion of privacy and violation of civil rights in the concept of liability. If the research activities summarized by Silverman violate one or more of these values, investigators may be considered to have abused a fiduciary relationship, ethically if not legally.

In a recent popular presentation entitled *Snoopology* (1975), John Jung discusses some probable effects of experimentation in real-life situations with persons who do not know they are serving as experimental subjects. These include: increased self-consciousness in public places, broadening the aura of mistrust and suspicion that pervades daily life, inconveniencing and irritating persons by contrived situations, desensitizing individuals to the needs of others by "boy-who-cried-wolf" effects so that unusual public events are suspected of being part of a research project.

At present a strong case can be made for the scientific value of field research using inobtrusive observation. But as the frequency of naturalistic experimentation increases, the usefulness of these procedures is bound to

decrease.

Referring to laboratory research, Seeman concluded (1969, p. 1026), "In view of the frequency with which deception is used in research we may soon be reaching a point where we no longer have naive subjects, but only naive experimenters. It is an ironic fact that the use of deception, which is intended to control the experimental environment, may serve only to contaminate it." In the long run this same argument will be applicable to naturalistic research. Referring to naturalistic experimentation, Jung concludes (p. 58) "psychologists are contributing toward their own downfall by establishing a credibility gap between themselves and the public. And the ensuing aura of mistrust and suspicion that would pervade daily life would be a high price to pay." Any research paradigm that precludes the right of the subject to give informed consent and exercise his right to receive an explanation and clarification of research findings may be in the long run self-defeating, as well as unethical.

In summarizing the few public opinion surveys on computers, privacy and record-keeping, Westin and Baker (1972, p. 468) state that "privacy-related issues are a matter of solid minority concern." About one-third of the respondents were distressed by what they felt was an erosion of their right to privacy. The public is aware of and appreciates the legitimate needs of government and industry for information, but Westin concludes (p. 388), and I agree, "that this would be a bad moment in our national history to adopt such a policy." There is in this nation today a high level of distrust concerning government surveillance and people fear that where such surveillance by government, industry or science is tolerated, repressive action might be directed against citizens. In countries such as Sweden, Norway and Israel, where such distrust does not prevail, privacy is not seen as an important manifestation

of civil rights. For many citizens and their government representatives in the United States, however, naturalistic observation and experimentation present the same danger as a citizen numbering system, databanks, and widespread psychological testing of school children; all these forms of inobtrusive surveillance are felt to violate individuals' rights to privacy and "inviolable personality," rights that can be waived but not abused, even by research investigators.

Legal scholars (e.g., Miller, 1971; Westin & Baker, 1972) encouraged by appropriate Senate subcommittees (e.g., Administrative Practice and Procedure, and Constitutional Rights) have been examining the computer-privacy question at least since 1967 when the National Data Center was proposed. These interested parties continue to urge lawmakers to consider the new information technologies and the effects computers may have on individual privacy in contemporary life. We may expect these watchdogs to continue monitoring evidence of the individual's loss of control over personal information, including unwanted intrusion through naturalistic experimentation in public or private places.

Strategies for Resolving Problems Associated with Use of Deception

Strategies deemed appropriate for resolving problems associated with deceitful practices depend upon the metaethical orientation one adopts toward the use of deception. From a utilitarian (cost/benefit) approach, deception is appropriate if the benefits outweigh the costs. Therefore, one may decrease the costs either a) by debriefing, and/or b) by avoiding unacceptable forms of deception (as determined by public opinion polling). Alternatively, one may increase the benefits *to the subject* a) by treating him with the respect due to a collaborator, and/or b) by reimbursing him with financial or other rewards. The absolutist approach rejects all justification of deception and requires the

investigator to develop new methodologies that do not require deception. All these strategies for dealing with the ethical problems associated with deceptive research practices will now be considered.

Decreasing Costs by Debriefing

The purpose of debriefing in research involving deception is to correct subjects' induced misperceptions about their own and others' performance and to reestablish conditions of trust in the professional relationship. There is some question as to whether even the most effective debriefing can reverse these undesirable aftereffects of deception procedures. According to section 8-9 of the APA Code of Ethics:

The investigator has the obligation to assure that research participants do not leave the research experiencing undesirable aftereffects attributable to their participation. Such negative consequences can arise if the participants are permitted to remain confused or misinformed about important aspects of the study or, more serious still, if steps are not taken to remove effects of psychological stress or other painful consequences resulting from research participation.

But as Seeman (1969, p. 1027) points out:

When a person is told that he has been deceived, he may quite conceivably be confused as to when the deception had really taken place. Since he will quite appropriately have lost confidence in the person's veracity, the subject may never be able to disentangle the times of truth and the times of falsity in his relationship to the experimenter.

For example, in the Milgram experiment, debriefing would not reinstitute the subject's self-image or his ability to trust adult authorities in the future. The subject did after all commit acts which he believed at the time were harmful to another, and he was in fact entrapped into committing those acts by an individual whom he had reason to trust.

It is my observation that investigators concerned about the effects of revealing deceptive practices are increasingly opting for leaving the subject uninformed or misinformed.

In my view the investigator must forego the opportunity to engage in

research that permits only two possible alternatives: *deceptive debriefing* (in which the truth is withheld from the subject because full disclosure would lower the subject's self-esteem or affect the research adversely); or *inflicted insight* (in which the subject is given insight into his flaws, although such insight is painful to him and although he has not bargained for such insight). In section 8-9 of the APA Code of Ethics concerning the obligation of the investigator to remove misconceptions about the subject himself or his performance in the experiment, whether these misconceptions have been deliberately or unintentionally induced, the question is asked but not answered: "Must the investigator correct misinformation or provide missing information even when this will be distressing to the participant?" (1973, p. 76)

The situation, as I see it, is this: the investigator, to further his own end (i.e., to do worthy research as efficiently and effectively as possible) contrives a predicament for himself where, as he sees it, he must choose between two equally unacceptable alternatives in his treatment of subjects, that is, deceptive debriefing or inflicted insight. The solution to this "dilemma" is simple. The investigator need only reject his original experimental design as unethical on the grounds that it allowed him only two alternatives, both morally unacceptable (i.e., that it placed him in a moral dilemma). He can then proceed to invent another and more ethically acceptable design. No experimental procedure anticipated by the investigator to require deceptive debriefing in order to guard the subject's self-esteem or mental health ought to be considered. For deceptive debriefing violates the subject's fundamental rights to have misconceptions removed subsequent to the experiment and to receive honest (although not necessarily complete) feedback concerning the findings of the experiment. The investigator's duty is clear. Just as he may not intentionally design an

experiment in which it is necessary to kill or maim the subject to facilitate effective and efficient research, so he may not design an experiment in which it is necessary to deceptively debrief a subject.

Concerning second order deception (i.e., deceptive de-debriefing), Kelman (1967) states,

Such a procedure undermines the relationship between experimenter and subject even further than simple misinformation...deception does not merely take place within the experiment, but encompasses the whole definition of the relationship between the parties involved. Deception that takes place while the person is within the role of subject for which he has contracted can, to some degree be isolated, but deception about the very nature of the contract itself is more likely to suffuse the experimenter-subject relationship as a whole and to remove the possibility of mutual trust. (p. 2)

Some, but not all, of the above objections to debriefing can be met provided that the investigator takes seriously his responsibility to offer subjects a reparational experience. Aronson and Carlsmith (1968) point out that debriefing requires considerably more than blatant exposure of the truth; subjects' reactions are in part a function of the experimenter's tact and consideration. The experimenter can express his own discomfort at using deception and explain in detail its necessity and the care that went into making the procedure believable, thus reducing the subjects' concerns about being found gullible. To the extent that subjects are permitted to gradually work out the truth for themselves, these writers believe that they will feel less victimized.

Mills (in press) emphasizes that the clarification procedure or debriefing may itself have harmful effects unless conducted with great sensitivity. He presents in great detail a debriefing procedure, including a scenario, which he developed over 20 years of debriefing and which he believes can be adapted to explain any experiment using deception. The advantages of the scenario are that the investigator is required to put a great deal of care

and thought into his presentation; he can proceed confidently, covering all necessary points so that the participant is provided with an educational experience as well as a truthful account of the experiment's actual nature. The experiment is explained very gradually and every point reviewed until the subject understands. The subject is then given time to reorganize his perception of the experiment and his responses to it, from possible humiliation and discomfort to self-acceptance and hopefully sympathetic understanding of the researcher's perspective. Certainly investigators, if they use deception, should be required to show subjects the respect inherent in Mills' scenario. It should be noted, however, that the script leaves no room for the subject to object to the morality of the deception and, indeed, makes it difficult for him to do so by providing such an air-tight rationalization for its use. For reactive subjects concerned with personal agency this could be quite offensive. But in most instances I would agree that such extremely careful and considerate debriefing could substantially reduce the costs of deception and increase the benefits to the subject of his participation.

Decreasing Costs by Polling the Public

Many social science investigators claim that most prospective subjects would not in fact object to the use of deception were they given a chance to vote on the issue.

There is an important sense in which polling the public does decrease the societal costs of the use of deception. By informing the public of the issues, polling actually promotes a sense of self-determination for the group as a whole, if not for each individual.

There are in fact a few studies which explore the question of how subjects feel about deception. For example, Sullivan and Deiker (1973) surveyed a random

sample of 400 members of the APA and 357 undergraduate psychology students to determine which group most harshly judged deception. Not surprisingly, more of the psychologists felt that deceptive practices were unethical than did the students. Given the greater maturity of adult judgment this would be expected. (The moral to be drawn from this study, in my opinion, is not that the use of deception is ethical but rather than undergraduate psychology students are still in need of ethical guidance.) More studies with other populations are needed.

I recommend, therefore, that where investigators plan to use deceit or where informed consent cannot be obtained, representative samples of people be matched with the individuals to be investigated to serve as peer consultants and to review the proposed experimental or observational procedures. These peer consultants, selected in the same manner as public opinion poll respondents, could assist investigators in identifying ethical problems and serves as informants to evaluate the effects of deception.

The public should know the kinds of risks a volunteer subject may expect to undergo. While in a general sense subjects would be less naive as a result of a publicity campaign, their set might also be more standardized and their behavior less suspicious in a given experimental situation. The cat and mouse element is reduced when subjects are encouraged to act "as if" the experimental instructions are straightforward. Investigators would realize that a "naive" subject is one who has agreed to suspend disbelief rather than one who presumably has been fooled into believing duplicitous instructions.

Increasing Benefits to Subjects

The investigator's indebtedness to subjects should be expressed in material payment and in focussed attention to the subject as a human being. The investigator seldom perceives in positive terms his indebtedness to the subject,

perhaps because the detachment which he thinks his function requires prevents appreciation of the subject as a person. Yet a debt does exist, even when the subject's reason for volunteering includes course credit or monetary gain. Particularly where experimental conditions expose the subject to loss of dignity or offer him nothing of intrinsic value, the experimenter is obliged to reward the subject with something the subject values. In addition to material rewards, the experimenter should make time to express his appreciation to the subject, answer his questions in detail, assure him that he did well, and exchange amenities. Subjects should be the first recipients of knowledge gained from the project--knowledge specifically about themselves and then about the questions the research is designed to answer. If a subject is seeking an opportunity to have contact with and confide in a person with psychological training these personal needs also should be met. To the extent that it is possible, subjects should be actively involved as collaborators in ongoing research. I will quote Eisner's excellent treatment of the debt owed to the subject and the way in which this debt can be repaid.

The social status of each subject renders him powerless within the research setting. Furthermore, the fact that experiments are carried out, for the most part, in the experimenter's laboratory, with his equipment, according to his rules, combined with the prestige and recognized expertise of the experimenter, further contributes to the power deficiency of the subject (Kelman, 1972).

Giving subjects input regarding the purposes and goals of research, and procedures, reduces the discrepancy between the power of the subject and experimenter, and simultaneously can alleviate certain ethical problems (Kelman, 1972; Mead, 1969), particularly in terms of the costs/benefits approach. First of all, potential subjects or their peers might be useful in pointing out the possible harmful effects of the research, in other words, in assessing costs. Secondly, input into goals affords the subject the opportunity to reap some of the benefits of the research. It may also make research intrinsically interesting for the subject, and possibly more relevant to his own life. This is particularly applicable in the case of action-oriented research (Chein, Cook & Harding, 1948). Involving the subject in a way which benefits him, gives validity to the application of a costs/benefits analysis of a given piece of research.

Among the social scientists who have advocated increased subject involvement are Kelman (1972), Parsons (1969), Mead (1969), Argyris (1968) and Wallwork (1975b). Granted, extending to subjects complete, or, perhaps even equal control over research would be impractical, if not impossible. Because of the investigator's specialized knowledge, he is far more competent in experimental design and methodology. In that area he must have the bulk of the power (Kelman, 1972). Argyris (1968) compares the relationship between subject and experimenter to that of employer and employee. Like employees, subjects do not want to take over, to run the whole project. They simply want greater influence and opportunity to participate in the planning. Actively involving subjects in research has methodological advantages as well. Subjects tend to be more cooperative if research is perceived to be relevant to their own lives (Argyris, 1968). (1975, pp. 68-70.)

Developing New Methodologies

In order to appropriately assess the cost/benefit criteria it is essential to identify worthy research objectives where investigators claim the use of deceptive practices is mandatory. I would suggest that the commissioners contract for at least one paper on this vital subject. However, the assumption that certain phenomena of interest cannot be investigated otherwise must be examined critically. In many cases where this claim is made deception may actually occur because investigators have come to rely on specific research designs based on deceit (as for example the Asch situation in the study of conformity) and because deception per se is viewed either as a prestigious methodological device or as a simple solution to research-design problems.

Brief mention will be made of new methodologies being developed as a result of dissatisfaction with traditional experimental methods or in response to ethical problems. This is not the place to assess in detail their scientific merit although that question is relevant to a cost/benefit analysis.

Role-playing has been suggested (e.g., Kelman, 1967) as a way of avoiding deceit. There is reason to believe that subjects frequently role-play naïveté whether asked to do so or not. But the effect of actually asking them to do so may introduce a different artifact; subjects may be able to role-play the direction but not the magnitude of particular behavior. Where role-playing

has been used there is some evidence that subjects can simulate gross but not subtle intervention effects in conformity experiments (e.g., Geller, 1970; Horowitz and Rothschild, 1970; Willis and Willis, 1970). Appealing as this "solution" is, there are good theoretical reasons to doubt the efficacy of role-playing as a substitute for the real thing. To the extent that a subject does not know how he would react in a given situation he cannot role-play realistic behavior; were such information available investigators could merely use introspection rather than experimentation to determine reaction.

Simulation, which is a special kind of role-playing may have greater potential as a substitute for deception. Perhaps the most famous experiment using simulation is Zimbardo's simulation of prison life (1973) where 24 volunteer subjects were randomly assigned to the role of jail guard or prisoner. The experiment was sufficiently successful in simulating loss of autonomy in "prisoners" and abuse of power in "guards" that it had to be terminated after 6 days.

Overt field research, using either structured situations or naturalistic observation followed by intensive interviews is, in my opinion, the method for avoiding deception and obtaining valid, representative, sound psychological data. Subjects can be fully aware they are being observed and even that the investigator may introduce stimuli intended to produce a range of scientifically interesting responses. While covert observation and staged occurrences create serious ethical dilemmas, overt observation of representative behavior is possible when subjects are given the opportunity to become accustomed to the observers, tape recorders and videotapes. My own research (Baumrind and Black, 1967; Baumrind, 1971) relies heavily upon field research supplemented by intensive interviews which probe attitudes and values relevant to already observed behavior. These interviews also allow for examination of subjects' feelings and

attitudes about research, the setting, their own reactions, and the relationships the investigator is studying. The fact that the interviewer has been a participant observer provides a shared focus of attention for the interview and decreases the likelihood of intentional misrepresentation or unintentional romancing by the subject.

Enforcement of Regulations Governing Protection of Human Subjects

Most social scientists have greeted the HEW guidelines with dismay and confusion. Investigators, with some justification, are complaining of harassment by university committees composed largely of lawyers whose main concern is with neither the scientific enterprise nor the protection of subjects, but rather with the protection of the university from suit. By sensitizing subjects to their rights and to the possibility of gain, these committees increase the probability that such suits will be brought. Both committees and investigators, for self-protective reasons, become overly cautious and concerned with following the letter rather than the spirit of the regulations and lose sight of the fact that the intention of the regulations is to protect the *subject*. "Major limitations upon scientific progress have been imposed by an overly restrictive interpretation of rules for the protection of human subjects. The integrity and privacy of the individual must be protected, but the procedures for insuring the welfare of the individual need not be so cumbersome and stultifying as currently practiced."²

Many investigators (including myself) feel that in operation University review committees fail to protect the welfare and rights of human subjects because that is not their primary aim. Their primary aim often appears to be protection of the institution from civil suit by subjects and/or harassment by

²Wayne H. Holtzman, Chairman, Final report of the President's Biomedical Research Panel of the Social and Behavioral Development Interdisciplinary Cluster, October 1, 1975.

HEW officials. Adherence to enlightened ethical principles and/or concern for the welfare of subjects are secondary concerns. As long as investigators and University committees experience themselves as in dire threat, which at present they do, these public servants will attend to their own survival needs first, and the welfare of the community second.

The research enterprise is in fact threatened on many fronts. Funds for all research, but particularly social and behavioral research, have been sharply reduced. The respect scientists traditionally enjoyed in the community has been undermined. In my view, some of the most fruitful investigations and creative investigators are most threatened by loss of financial and social support. In social and behavioral science, the major important recent findings (as the President's Commission's final report of the Social and Behavioral Development Interdisciplinary Cluster concludes) are an outgrowth of longitudinal studies. But studying the same individuals repeatedly requires continuity of support and dedicated application of research skills for several decades. Without advance commitment of long-range support, longitudinal programs cannot be effectively pursued. Creative researchers, motivated by dedication to knowledge and by personal autonomy, are the real victims of restrictive regulations and punitive sanctions. For it is they, more than those for whom research is merely a means of attaining material and social rewards, who suffer the loss of the intrinsic rewards of the research enterprise itself.

Perhaps the most serious and legitimate concern behavioral scientists have about pressure from Washington is that it is frequently political in form. Pressure may be from the right or the left. Many investigators believe that the liberal ideology of most social scientists has resulted in punitive action from a conservative administration in the form of reduced funding and general

harassment. Other investigators are more concerned about pressure from the left suppressing lines of investigation whose results may prove politically embarrassing. Genetic research is a particularly sensitive area because of its capacity for revealing differences between groups of people in socially valued attributes. For example, in Boston last year, public pressure forced cancellation of an investigation of an acknowledged reality, the "X Y Y syndrome"; there occurs in roughly one in 1000 males an extra sex chromosome, labeled Y, which limited statistical evidence suggests may be associated with anti-social behavior. A group known as Science for the People, aided by other activist critics, was able to exert sufficient political pressure to force the investigators (Walzer and Gerald) to truncate their research program.

Similarly, a category called "social risk" was invoked by the Small Grants Section of the NIMH to effectively block normal peer review of two separate grants on the basis of "apparent failure to consider the probable social consequences of the study." One of the censored studies (Littman) proposed to study exploratory behavior in order to detect individual differences in social and intellectual competence among mildly retarded children. The second (Horn), proposed a secondary analysis of data on 624 white children and 209 black children in a study of "fluid" and "crystallized" intelligence. Here, two so-called ethical principles were invoked to censor his proposal--one, that consent for the secondary analysis had not been obtained from the original subjects, and the other, that a social risk to the class of which the subjects were members existed. I regard these two "ethical" rules and the use to which they were put as examples of harassment at best, serious violations of academic freedom at worst. Hopefully neither the principles governing protection of human subjects or the enforcement of these principles will continue to be used to create an atmosphere of vigilantism and scrupulosity. I strongly recommend to the Commission that

it take steps to see that effects of its actions are positive and do not create a new self-perpetuating bureaucracy whose immediate victims are innovative scientists.

Yet, as I documented at the beginning of this essay, social scientists have not given evidence that they can be trusted to regulate themselves to safeguard the rights and welfare of human subjects (witness the attached code of the American Sociological Association). Most do not believe that deceitful practices and failure to obtain informed consent constitute serious ethical violations. Most would probably agree with the sociologist Paul Reynolds (1972, p. 697) that among the examples of ethical problems cited by the APA "there is not a single instance of any individual suffering permanent damage as a result of participation in 'psychological' research;" and furthermore that (referring to APA guidelines) "it is difficult to justify such an elaborate set of principles to guide research."

Moreover, the guidelines (APA and HEW) themselves facilitate abuse of the rights of human subjects by a) requiring informed consent and restricting the protection of the rights and welfare of subjects *only* to those likely to be at risk, and b) permitting risks to an individual provided it can be shown that those risks are outweighed *either* by the potential benefit to the individual *or* by the importance of the knowledge to be gained.

Regretfully, I must conclude that effective external regulations and sanctions are necessary. How can they be made less onerous and more acceptable?

I recommend that the same structure which imposes sanctions against unethical practices also *assist investigators in accomplishing their legitimate objectives using ethical means*. When an investigator encounters a problem he believes requires the use of deceit, manipulations or noninformed consent, he should be able to submit his predicament to a peer group for help in devising

more ethical procedures. If this is unsuccessful, an ombudsman should be available to represent the investigator's position to the ethics committee.

A widespread educational campaign to inform the public about the social role and value of scientific enterprise as well as the ethical dilemmas scientists face in conducting their work should be mounted via the media. For example, citizens can be invited to respond to a graphic public opinion survey similar to the one successfully mounted by social policy planners responsible for the development of Yosemite National Park. More than 40,000 Californians clamored to participate in the formation of a master plan for the park by completing a very lengthy questionnaire composed of a very specific set of questions with action implications. A similar questionnaire-substitute for the town forum could be used nationally both to educate the public and to determine its present views on procedures and policy to be instituted for the protection of human subjects.

The decision as to kinds of procedures to be prohibited, regardless of the potential benefit to society, belongs to the lay public. As yet we do not know whether the average citizen, if informed, would require informed consent and prohibit deceit regardless of potential social benefits. It is past time that we found out.

Equally important, *a widespread educational campaign aimed at the profession*, perhaps sponsored by the Commission, should be mounted to encourage discussion of the ethical issues which the Commission itself is considering. Few members of University committees for protection of human subjects are ethicists by training or interest. While departmental chairpersons and graduate advisors are responsible for supervising students' research, few of them understand the ethical issues involved. The most serious ethical violations now occur in graduate students' research. These students are seldom offered

a course in ethics. I recommend that all persons involved in research on human subjects, or review of such research, be invited or required to attend seminars taught by ethicists who examine these issues.

Perhaps the most effective pressure that could be put on investigators is the knowledge that *editors would reject reports based on unethical research* where informed consent is not obtained or deceit is used. At present there is little evidence that editors or consulting editors include ethical considerations among their criteria for publication.

The operation of institutional review panels must be improved. On the one hand, investigators must be protected from unwarranted interference with the efficiency of their operation and de facto censorship. On the other hand, the regulations themselves must effectively prohibit research activities that violate subject's rights or their welfare.

Conclusion

Perhaps the seminal problem in social and behavioral research is that not all investigators do in fact respect their subjects as persons or appreciate their contribution to the research endeavor. If respect could be assumed--or if it could be taught as an integral part of the social scientist's professional education--then neither the Commission for whom this report has been prepared nor the various ethical codes of the professional societies would be necessary. However, the very existence of ethical codes indicates that trust and respect have eroded to the extent that they have had to be replaced by formal contractual agreements, and even these are far from satisfactory.

An examination of the Code of Ethics of the three major social science organizations reveals their established attitudes toward ethical regulation. The code of ethics of the American Sociological Association appears to me cynical and self-protective; the organization tries to defend itself from

external regulation and issues a declaration of professional independence. The American Psychological Association has produced a balanced, literate and profusely illustrated document which reflects but does not seriously attempt to resolve the fundamental differences that exist among psychologists. The body of the document provides varied and exquisitely detailed rationalizations and procedures for violating the 10 clear-cut ethical principles enunciated initially. The statement of the American Anthropological Association is an idealistic, ethically sensitive, and socially responsible document. It asserts affirmatively the absolute obligation of its members to place the interest of the subjects before their own and before those of science, and to use their scientific findings in the service of all humanity. However, it considers none of the intrinsic problems of anthropological research. (e.g., in obtaining informed consent does one abide by the code of an authoritarian tribal society which places no intrinsic value on the individual, or by a Western ethic that ostensibly does?) Nor does it explore the reasons why so many third world societies have rejected the attentions of anthropologists as intrusive and invasive.

Alas, if only all men were of good will, the AAA code of ethics would suffice to remind us of our higher values and common humanity. But just as subjects' motives for participating in research range from the prudential to the principled, so do investigators'. Investigators' motivations may include the desire to dominate and control interpersonal situations. Unless sublimated appropriately, these motives can stimulate dehumanizing behavior toward subjects and rationalize that behavior in terms of scientific detachment and rigor.

In view, then, of the social, political, and scientific realities of twentieth century America, it would seem that we have no choice but to

substitute some code or contractual agreement for the trust and respect which should, but can no longer be assumed to exist among human beings. All human activities are permissible in the proper time and place. There is a time for deceiving, as there is a time for hating and for killing. The question concerns time and place. It is the special characteristics of the research setting that put subjects "at risk" in ways they would not be in ordinary life. The use of deception in research, precluding--as it does--informed consent, cannot be justified today. The threat to privacy and to individual constitutional rights posed by computer technology and electronic surveillance devices in the hands of government and industry executives is too grave in contemporary American society to legitimize any justification of violations of constitutional rights. Social, behavioral, and medical scientists have not demonstrated that the legitimization of such violations in order to obtain information and knowledge would produce benefits that outweigh the costs to society. In fact, they have failed to demonstrate, as yet, that important scientific objectives are precluded by an absolute prohibition against deceitful practices. It is essential that they be given a chance to do so. If it could be demonstrated that in all probability a socially useful scientific objective could not be attained without the use of deceitful practices, I believe that, given an opportunity to decide, most segments of the community would consent to the controlled use of deceptive practices to obtain that particular objective. I personally would not consent, nor would I intentionally use such practices even were the community to consent. But neither would I prohibit their use, because explicit collective consent by citizen groups substantially lowers the probability that individuals will lose trust as a result of deceptive practices or that their right to liberty and self-determination would in fact be threatened by such practices. Also I am concerned that stringent external regulations

will drive many creative, intrinsically motivated scientists to abandon their research endeavors.

However, proscriptions against social science methods which violate ethical principles may be exactly the impetus required to induce a paradigm shift in social psychology away from the study of subjects as objects to the study of subjects as active agents. There is evidence that psychologists on both sides of the Atlantic are already moving in that direction (Armistead, 1974; Smith, 1974). To the extent that investigators treat subjects as though they are purposive, active, self-reflective persons trying to construct meaningful experiences for themselves within as well as without the investigator's small world, they may become so. New research designs better suited to understanding men and women as active agents engaged with their social environment can be developed in response to the ethical and methodological limitations of our traditional methods.

APPENDIX A

Examples of the Use of Deception Drawn Mostly from the Family Socialization Project (Baumrind)

Here I will illustrate the kinds of ethical problems that have come to my attention in the last few years, all of them but the first drawn from my own research.

1. *An undergraduate student studying nonverbal communication.* This fairly typical example illustrates rather well how little attention is paid to ethical issues by instructors in charge of training undergraduate and graduate students. In 1974 a competent undergraduate at the campus of the University of California wished to study nonverbal communication. She devised a gadget for recording instances of behavior which interested her; this gadget could be operated without the knowledge of the subject. She recruited student subjects on the pretext that she wished to interview them concerning their social and political attitudes and then recorded secretly their nonverbal reactions to the interview questions. It should be noted that her faculty sponsor did not raise the ethical issue with her. However, during the course of her study several friends questioned the ethics of her procedures, which led her to wonder how her subjects would feel if they *discovered* that they had been duped. Since it was a small campus, she was sure some subjects would make that discovery. The student, like many more mature investigators, felt that the real harm to the subjects would come from the debriefing itself. Therefore, she never debriefed her subjects. Was the scientific value of her study sufficient to justify the use of deceit and failure to debrief? She had never raised the question, nor had any of her instructors; I was the first to do so. The student learned to regard the use of deception as normative, and covert observation as acceptable. The methodological requirements of her study did in fact

necessitate concealment. But there were ethical ways in which the concealment could have been accomplished. For example:

a) Subjects could have been selected from amongst those who agreed to accept the instructions as given, with the understanding that, as is true in many experimental situations, the entire truth might be withheld and they would receive a full explanation of the objectives of the investigation subsequent to the study. S's given such instructions easily suspend disbelief since what they are suspicious about has been admitted candidly from the beginning.

or b) Nonverbal cues could have been recorded inconjunction with an actual social survey conducted for bonafide purposes by another investigator. Debriefing would include acknowledgment that additional information had been collected. Consent after the fact would be obtained from all subjects who were retained in the unlikely event that any S objected to having such complete data about his or her behavior collected.

2. *A graduate student using a modified Prisoner's Dilemma Game in my research project.* A second example is described by a graduate student whose dissertation I helped to supervise. His account is as follows:

I encountered an ethical problem in my doctoral research when I decided to use a modified Prisoner's Dilemma Game. The game was played by two subjects at a time at computer terminals. The subjects were nine-year-old children. In order to establish a baseline for each child's level of cooperation, I planned to present each subject with a standard sequence of plays stored in the computer. Then, to measure the children's interactive play, I planned to present each child with his or her partner's actual choice. My initial plan was to deceive the children by telling them that they would always be playing with their real partner. Dr. Baumrind, one of my dissertation advisors, refused to go along with this on the grounds that to falsify the children's perceptions of their social interactions was wrong. We cast about for a solution that would preserve the experimental design and that would also be free from deception. The solution which was actually applied was to inform the children that as they played, part of the time their partners would be real (i.e. human) and part of the time the computer would be their partner. I added that, since they would not know when they were playing with the computer and when they were playing with

their real partner, they should play *as if* they were playing with their real partner. Thus, although the children were left in doubt until the end of the experiment as to who their partner was, they were not deceived. In fact, for the first 125 of the total 200 tries, subjects were playing against a computer.

Questioning after the game indicated that all of the children understood the actual situation. The children's comments and the data that emerged from this experiment were consistent with those of colleagues who used deceptive instructions; so that in this instance deceitful instructions appear to have been unnecessary to accomplish my experimental objectives. The information obtained during the 75 trials when the child was engaged in truly interactive play yielded information interesting in its own right.

My concern here was that if the children were deceived from the beginning the experimenter would have an untenable choice during the debriefing process-- either he would have to tell the children they had been deceived in the first place, thus positively sanctioning the practice of deception by an adult authority, or he would have to forego debriefing altogether in which case the children would leave the experimental situation misinformed concerning the extent to which their peers used cooperative or competitive strategies. My judgment was that in either case the child's own ethical judgment would be affected adversely, and that the risk no matter how small could not be justified by any gain in knowledge accruing from the experiment to the subject.

3. *My own research--observing children in the school setting.* We routinely collect information on each child in the school setting. The information we collect might be more representative if the children did not know they were being observed. However, for ethical reasons our practice is to obtain the children's explicit permission to make school visits although we have already obtained full consent from their parents. Therefore, we interview the child *prior* to the first school visit, and at the end of the interview obtain his permission to make a series of school visits. But incidental to our observations of the subject child, we do take notes on other children who are part of his environment. These children not in our study on whom information is collected

incidentally, are not told that they are being observed. It is our judgment that to do so would burden the students. The child might then become self-consciously concerned that any visitor in the room was observing him, even those he did not know or with whom he had not established a relationship. Since our choice was to distress the children by asking their permission, to not make school visits at all, or to fail to make full disclosure, we chose the latter alternative. Since the children are in no way distressed or deceived by our presence alone, we regard our "failure to make full disclosure" as acceptable although not exemplary, and continue to observe the child subjects in their school settings.

4. *My own research--active withholding of information.* In order to protect a sensitive and self-conscious child, we have had occasion to withhold the whole truth from other children who asked about our purposes in the classroom. The partial truth we tell them is that we are there to learn more about how classrooms differ. This partial truth is intended to deceive and is, therefore, a lie. When one child thanked the observer for lying in order to save him embarrassment, we acknowledged that we had done so for that purpose. We do not regard telling a "white lie" (i.e., a lie intended to prevent discomfort) to a child as setting a bad example. Since we had created a situation in which the child was placed "at risk", we felt we had the responsibility for minimizing that risk although to do so involved deceit. The implicit contract with the subject-child is that we will relate to him or her in a supportive and partisan fashion and that is what we do. It was our judgment that the telling of a partial truth to the other children did not place them at risk, because it is understood by school children that adult strangers need not take them into their confidence by revealing their full intentions.

5. *My own research--lying thoughtlessly and unnecessarily.* On occasion in our research, we find ourselves lying unthinkingly and for no good reason.

For example, one of Flavell's role-taking tasks is administered as follows-- and we followed the standard instructions until we thought more about it. E_1 displays a series of seven pictures and asks S to tell the story which they illustrate. Three specific pictures are then removed, E_2 enters the room, and S is requested to predict the story which E_2 would probably tell from the remaining four pictures. S is told that E_2 has never seen the whole series of seven pictures. This is of course a lie and an unnecessary one at that. Incidentally, it is not believed by most bright children. (In fact, a child brought to our attention that we were lying by saying "Aw, come on, how long has [E_2] been working here?!") It is sufficient for our purposes to instruct S to predict the story E_2 would probably tell *if* he had never seen the remaining four pictures. The added advantage of this procedure is that the set for all S's is standardized.

6. *My own research--lying by implication.* It is our practice to film a family discussion situation. The family is told explicitly that they will be filmed. However, prior to the full family discussion in which both parents and the subject discuss the Kohlberg moral judgment stories, the parents have fifteen minutes together in which they plan their approach. For months we overlooked telling the parents that this portion of the interaction was being filmed. Since we had been so honest with them about our procedures and intentions, they assumed that we would have told them if they were being filmed. It happens that one of the videotapers was aware that the parents were being misled into thinking that they were not being filmed. He felt that the information thus obtained was particularly valuable because it appeared so informal--the family is in a living room setting and no observers are present--and that to tell them they were being filmed would reduce the informality. He did not feel that by

saying nothing he was lying. Once I became aware of the situation, parents were from then on informed.

I present these rather trivial but typical instances of the use of deception to illustrate how ubiquitous the use of intentional and non-intentional deceit is even when the investigator is sensitive to ethical issues, and also to suggest that in most instances deceptive practices can be eliminated and the objectives of the research nonetheless achieved. I also wish to illustrate that it is not deception in a vacuum which is ethically unacceptable; it is the violation of the subject's basic rights, particularly the right of self-determination, which so often occurs with the use of deceptive practices that cannot be accepted on ethical grounds.

Postscript

In my final re-rereading of this paper I note that despite my objections to the implications of the term "subjects" I continue to use that term to refer to participants. This is not only logically inconsistent and revealing, but has the effect of reinforcing a public attitude towards participants which I contend should be changed. In the event that this paper is published by the Commission I request, therefore, that the word "subject" be changed to "participant."

APPENDIX B

Procedures for Obtaining Informed Consent Used by the Family Socialization Project (Baumrind)

Participation is solicited by telephone from prospective subjects. Those who are willing to explore further the possibility of participation are sent a lengthy summary of procedures in which they would be expected to participate were they to consent. This is followed up by a visit to their home in which all family members are present. At that visit the procedures are explained further to the parents, and those that affect them are discussed with the children. There are three separate consent forms, all appended. One consent form, to be signed by both parents, signifies agreement with the procedures described. The second consent form is in the form of a letter to the child's principal and teacher requesting their cooperation. Willingness to sign this letter signifies a high level of commitment to the project. There is a third consent form for use of case history material.

Note that the child's written consent is not obtained at this age (ages 8 or 9) and that none of the consent forms specify possible benefits or costs. These considerations are discussed during the home visit. The following description of costs and benefits is provided the University Review Group.

Effects on Subjects

Beneficial. The relationship with subjects is collaborative. In addition to the information about family processes which subjects provide, their critical abilities are harnessed to our own in revising measures. Parents are given copies of the self-report and other measures in order that they may continue to explore in their own minds the child rearing and value issues which these measures assess. Lengthy conferences are arranged

with each family to provide feedback. In addition, an honorarium of \$150.00 is given to each family.

Potential drawbacks.

1. *Invasion of privacy.* Our procedures include invasion of the privacy of the homes. Protection of subjects is afforded by selection of observers who are courteous, supportive, tactful, and professional in their demeanor. In order to assure confidentiality, data are converted to IBM cards and data tape. In this form the subjects are fully anonymous.

2. *Deceit.* We avoid the use of procedures which require deceit or covert observation, even where to use these procedures would provide us with more valid data. For example, observers are instructed to interview the child *prior* to school visits and to obtain the child's consent to these visits, even though observation would be more "naturalistic" if the child were not aware that he was being observed. While we tape behind a one-way mirror, all family members take their turn observing behind the mirror so as to assure their full awareness as to what can be seen and heard.

3. *Unanticipated self-knowledge.* The intensive interviews concerning moral judgment and child rearing practices will initiate in some parents a re-examination of their own values. For a few this self-examination may initiate insights and changes which would be facilitated by discussion with a psychologist. We have a person on our staff to perform this function.

Benefits To The Lay And Scientific Community

Characteristics of this program of research which contribute to its scientific significance are a) in-depth collection of data using multiple settings and measures over time; b) the use of an extensive battery of objectively scored tests and videotape transcripts to supplement the ratings; c) the longitudinal nature of the data collected; d) the fact that the sample studied is from the

San Francisco Bay Area, an area of the country where secular changes are first felt so that the relationships noted should have predictive significance for the rest of the country; e) dimensions of child-rearing and of child behavior are studied configurally rather than in isolation thus permitting important distinctions between parents and between children to emerge.

The focus of the program of research is on patterns of parental authority, an area of acknowledged social importance, particularly today. The way in which authority has been conceived and exercised has been one of mankind's constant concerns through the ages and assumes particular interest in a period of rapid social change.



INSTITUTE OF HUMAN DEVELOPMENT

Family Socialization and Developmental
Competence Project

EDWARD CHACE TOLMAN HALL
BERKELEY, CALIFORNIA 94720
AREA CODE 415 642-3603

PERMISSION FORM

Name of child _____
(please print)

I have read the SUMMARY OF PROCEDURES which you provided. Our family is willing to participate in this phase of the study, and you have our permission to perform the procedures listed. You also have our permission to videotape some of the procedures for use by members of the research staff only. I understand that no use other than coding and analysis of data by the staff will be made without my specific, written consent.

Signature of mother _____

Name _____
(please print)

*Social Security No. _____

Signature of father _____

Name _____
(please print)

*Social Security No. _____

Address _____

Phone _____

*For payment of Honorarium.



Institute of Human Development

Family Socialization and Developmental
Competence Project

1203 Edward Chace Tolman Hall
Berkeley, California 94720

TO: My Child's Principal and Teacher

Our family is participating in the Family Socialization and Developmental Competence Project (a study affiliated with the Institute of Human Development, University of California, Berkeley, directed by Diana Baumrind, Ph. D.). The study is concerned with the childrearing attitudes and behavior of parents and their effects on the development of their children.

One of the project's interests is to evaluate how the child adapts to his/her particular school environment. This would involve an observer paying about three visits to our child's school and observing classroom and playground situations in which our child participates. We have already granted the project our permission to do so, if this meets with your approval. If you have any questions as to what this will involve, please call Dr. Baumrind's office, 642-3603, from 9 to 5 on week days, and an observer will be glad to answer your questions.

Sincerely yours,

Signature of Parent

Name (Please Print)

Child's Name (Please Print)

Address

School

Grade



FAMILY SOCIALIZATION AND DEVELOPMENTAL COMPETENCE PROJECT
INSTITUTE OF HUMAN DEVELOPMENT

1203 EDWARD CHACE TOLMAN HALL
BERKELEY, CALIFORNIA 94720
AREA CODE 415 642-3603

To: Participant families in The Family Socialization and Developmental Competence Project
(Formerly The Parental Authority Research Project)

From: Diana Baumrind, Ph.D.
Principal Investigator

Re: Consent for using case history material

Up to this point, data on families have been converted to quantitative scores that yield generalizations similar to the following: "The use of mild forms of corporal punishment is not associated with any symptoms of maladjustment in the families studied" or "When parents require the child to participate in household chores, the child is relatively independent and self-assertive." When findings are reported in such a manner, reference to individual cases is unnecessary. Because of the richness of the data and their longitudinal nature, we are finding that we would like to be able to use the data in additional ways. In order to do so, we believe that we should first obtain consent from each family for each possibility. So that we will know what "case history" data are available to us to use, we are asking that you check the following and return the sheet to us. IF EITHER PARENT OBJECTS, PLEASE RESPOND IN THE NEGATIVE FOR THAT QUESTION.

The videotapes of the family discussion illustrate the ways in which people communicate in arriving at decisions.

1. May we show excerpts from the videotape of your family discussion (or parent teaching) to seminars of graduate students or meetings of professional colleagues to illustrate ways in which different families arrive at decisions?
Yes _____ No _____
2. In articles prepared for a professional audience, may we include brief descriptions of the content of the tapes to illustrate family processes? Names and similar identifying data are omitted.
Yes _____ No _____

In order to enrich our discussion of findings in journal articles, we would like to be able to include brief excerpts from interviews or home visits. In all cases identifying data are omitted.

3. May we use such excerpts from our notes of the home visits or transcripts from the interviews with your family?
Yes _____ No _____

NAME OF FAMILY _____

SIGNATURE _____

DATE _____

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SOME COMPLEXITIES AND UNCERTAINTIES REGARDING THE
ETHICALITY OF DECEPTION IN RESEARCH
WITH HUMAN SUBJECTS

Leonard Berkowitz, Ph.D.

Some Complexities and Uncertainties Regarding the Ethicality
of Deception in Research with Human Subjects

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One of the most complex methodological problems confronting the sciences engaged in research with humans has to do with the ethicality of deception. Yet recent cultural trends have made us more conscious of this problem than ever before and press for a relatively quick solution. There has been a renewed emphasis on the value of human dignity and the right of the individual to be free from arbitrary coercion in the past several years. Perhaps more than at any time since the Great Depression we as a people insist on the desirability of individual autonomy. Revenue sharing, suspicion of big government, the mounting distrust of politicians, and the spreading popularity of the economic notion that "small is beautiful," among other things, testify to the growing belief that a person should have more control over what happens to him.

I do not mean to question these ideas or argue that the contemporary interest in them is only a passing fad. However, it is all too apparent that the current concern with individual dignity and autonomy has led some people to be highly critical of behavioral science and especially of laboratory experimentation with humans. In their estimates of the possible costs and benefits of this research these critics tend to give relatively little weight to the favorable consequences that might result. At the same time, they stress and perhaps even exaggerate the risks to the research subjects.

From their perspective it is necessary to establish firm guidelines, if not restrictive rules, for behavioral science investigators in order to protect the rights of the subjects and minimize the injuries that might be done to them. I will try to argue in this essay that it is virtually impossible to set up a screening agency that will assess the relative costs and benefits of a given experiment with any substantial degree of validity, and also, that attempts to create a board of monitors which will closely scrutinize all research for every conceivable threat to subjects will seriously impede the development of behavioral science. In a sense, this paper is a brief in support of experimental behavioral science. It would permit the practices that most laboratory-oriented behavioral scientists follow today, including reasonable deceptions. Since other writers speaking to the Commission will emphasize the risks and ethical difficulties inherent in the use of ruses, partial truths, and downright misleading statements in experimental research, my own argument, brief-like, will downplay these costs. As a consequence, it may seem that I do not believe there are any problems or dangers in stressing and deceiving research participants. This is not the case. I do feel, however, that some of the objections to the investigations being carried out by contemporary experimental behavioral scientists are exaggerated.

Several prominent social psychologists have voiced misgivings about the widespread use of deceptions in laboratory studies. To sample just a few of these objections, a generation ago Edgar Vinacke (1954) expressed concern about experiments in which "the psychologist conceals the true purpose and conditions of the experiment, or positively misinforms the subjects, or exposes them to painful, embarrassing, or worse, experiences, without the sub-

ject's knowledge of what is going on." He wondered what "is the proper balance between the interests of science and the thoughtful treatment of the persons who, innocently, supply the data?" Vinacke seemed to imply that social psychologists all too frequently treated their research subjects in a non-thoughtful, perhaps even inhumane, fashion in their pursuit of their scientific objectives. Some years later Herbert Kelman (1967) raised the problem anew in a thoughtful and fairly moderate critique of the "unquestioning acceptance" of the "routinization of deception" that exists in experimental social psychology. Kelman recognized the necessity of misleading subjects about the true nature of the research in some types of studies. "There are many significant problems that probably cannot be investigated without the use of deception," he noted. However, he wondered whether social psychologists have the right "to add to life's little anxieties and to risk the possibility of more extensive anxiety purely for the purposes of our experiments." The explanation (debriefing) typically given to the subjects at the end of each laboratory session might not, he thought, adequately remove all of the harmful effects. Milgram's well-known experiments on obedience to authority are an excellent case in point. Even though the obedient subjects were told afterwards that they had only been in an experiment and had not actually shocked anyone, Kelman argued, "there is good reason to believe that at least some of the obedient subjects came away from this experience with a lower self-esteem, having to live with the realization that they were willing to yield to destructive authority to the point of inflicting extreme pain on a fellow human being." Even if the experience provided these people with an opportunity to learn something of

importance about themselves, as Milgram maintained, do we (Kelman asked) "have the right to provide such potentially disturbing insights to subjects who do not know this is what they are coming for?" The same thing can obviously be said about much less stressful research such as conformity experiments. Is it proper for the investigator to affect his subjects' self-esteem by showing them that they were easily swayed by the fictitious group pressure?

Kelman's question about the ethicality of deception research rested largely on the possibility of long-lasting adverse consequences. The subjects might suffer a fairly persistent injury to their self-concepts or experience a continuing anxiety that is not remedied by the experimenter's debriefing at the conclusion of the session. But in addition, he also wondered if the lies and tricks used in social psychological experiments did not also color the subjects' views of the world around them. They learned that they had been manipulated by the experimenter's deceptions and this lesson could reinforce other demonstrations, all too prevalent today, that man is an object to be manipulated at will by societal institutions. "In institutionalizing the use of deception in psychological experiments," Kelman contended, "we are, then, contributing to a historical trend that threatens values most of us cherish." The Ad Hoc Committee on Ethical Standards established by the American Psychological Association (the Cook Committee) summarized this type of argument in these words:

"One frequently hears it asserted that behavioral research is contributing directly to the moral ills of society. According to this argument, when an investigator invades the privacy of another person, employs deceit, or occasions pain or stress, he contributes to legitimizing these indignities, and therefore to their prevalence in interpersonal behavior." (Cook et al., 1973, p. 17).

This accusation is a very serious one, especially given the prevalence of deception in personality and social psychological research. A good many studies in these areas attempt to mislead subjects about important aspects of the investigation they are in. One count of 390 published reports in personality and social psychology (Stricker, 1968, cited in Silverman et al., 1970) found that participants were "intentionally misled" in 21% of the studies. This is probably a minimum estimate of the frequency with which subjects are deceived. As Aronson and Carlsmith pointed out (, p. 30), mild deceptions can be very subtle and common--such as misinforming people about the true purpose of a personality test they are taking (for example, by introducing the TAT as a test of creativity) or behaving in a pseudo-friendly manner to the subjects in order to make them more cooperative. Can these widespread practices be defended? Should the researchers employing these procedures be subjected to stringent controls established by some outside agency?

I would like to start this defense of the judicious use of deceptions in behavioral experiments by taking up the last two concerns I mentioned: first, whether subjects generalize from the experimental situation to other conditions of life and then, second, whether the experimenter's debriefing can alleviate many of the ill effects of the experiment. The discussion will then turn more directly to the matter of informed consent and will consider the kinds of information that should be given to the prospective participants in soliciting their cooperation.

Kelman believed that social psychologists are shortsighted when they differentiate between the laboratory and the surrounding world. "We tend to re-

gard the [laboratory setting] as a situation that is not quite real, that can be isolated from the rest of life like a play performed on the stage, and to which, therefore, the usual criteria for ethical interpersonal conduct become irrelevant" (Kelman, 1967, p. 5). Kelman is quite right in one sense; social psychologists are inconsistent if they view the laboratory situation as "not quite real" and still extrapolate their findings to other social settings. He is incorrect, nonetheless, in thinking that investigators defend their practices on the grounds that the laboratory "can be isolated from the rest of life." The laboratory does not really have its own rules of conduct. Most subjects believe that an experimenter's actions are governed by overriding standards, general rules that an investigator is expected to follow, much as everyone else also follows rules. Thus, according to evidence gathered by Epstein, Suedfeld and Silverstein (1973), research participants typically feel that an experimenter is primarily obligated to provide clear instructions, insure the subjects' safety and warn them of danger. He apparently is not expected to be truthful in every detail. It may well be, as many researchers believe, that subjects do regard the experimenter's statements to them as morally appropriate. The rules of his scientific enterprise, which they generally recognize, permit him to mislead them, and he is keeping to these rules. For many of them, the larger context within which the study is carried out serves to justify the deceptions, partial truths and stresses to which they had been exposed.

While I agree with the Cook Committee (1973, p. 17) that further research is needed to determine what standards should govern the experimental procedures, my own experience over more than two decades of laboratory investigations

with university students is entirely consistent with the statement I have just made. Many of my experiments in recent years have deliberately provoked subjects so that we could study the conditions influencing their aggressive responses. Other social psychologists have conducted similar investigations. But despite all of the frustrations and insults administered to thousands of subjects, I have not heard of any complaints about these treatments being voiced to university authorities at Wisconsin or elsewhere. There certainly have not been any protests sent in to our fairly radical student newspaper about this type of research. Of course, a few students might have resented the treatment they received, but I suspect this was quite infrequent, perhaps surprisingly so from the point of view of some critics, and even then was very mild. There are good reasons for this, some having to do with the debriefing--and I will go into this shortly--and others with the perceived legitimacy of the experimental treatments. When the subjects learned at the end of the session what had been done to them and why, the great majority undoubtedly readily grasped the significance of the research. They also regarded the experimenter's behavior as justified within the context of his scientific activity. The provocation had not been directed against them personally, they realized, but was in keeping with the implicit rules of a social-psychological experiment, and was therefore "de-emotionalized." My firm belief is that for the preponderance of university students the scientific context of the experiment similarly "de-emotionalizes" many different kinds of stress that they might have experienced in the course of the study.

The subjects understand this scientific justification when they finish participating in the study and the researcher explains his purposes and methods. The debriefing places the experimental experience in the appropriate context. Contemporary theoretical analyses of emotions as well as several recent investigations of the consequences of debriefings suggest that these after-the-fact explanations can do much to lessen the unpleasantness of whatever stresses and strains have been imposed on the subjects.

These results are not particularly surprising. But I think they parallel what often happens in some kinds of psychological experiments when the experimenter debriefs the research participants. Here too, the subjects are provided with an explanation that changes the meaning of the threat to which they had been exposed in the investigation. They now learn that they had not really been confronted by a test of how well adjusted they are or an assessment of their personal adequacy or a deliberate insult to their self-esteem. Perhaps equally important, they find that what had seemed like an arbitrary assault directed at them personally was actually an impersonal treatment administered to all of the people in their experimental condition. The event that had previously aroused anxiety or anger is now viewed in a very different manner, is "de-emotionalized" as I said before, and the subjects' emotions subside fairly quickly.

The debriefing can also cause the subjects to reinterpret their own behavior in the experiment. Earlier in this paper I quoted an argument that Milgram had employed to defend his research on obedience to authority: his participants had learned something about themselves--they had a tendency to

submit to authority. However, as Kelman (1967) noted, the subjects might not have wanted this kind of insight. In the same vein, Baumrind (1964) pointed out that the subjects could have suffered a blow to their self-esteem on realizing the full significance of their action. While the self-awareness arising from some experimental situations could well produce a certain amount of unhappiness, my experience with experiments on aggression suggests that it is possible to minimize this distress with an appropriate explanation. Instead of focusing on what the individual himself/herself had done, our debriefings clearly indicate (quite accurately) that we are not at all interested in the subject as a distinct person; we only want to know how students in general behave under the conditions of our experiment. Moreover, the subject is also assured (and again, this is usually a fairly accurate statement) that quite a few other people had acted in a similar way. Perhaps this is a commentary on the state of ethical judgments in our own society, but many persons are evidently not too unhappy about the improprieties they have committed if they are told that their behavior is quite common. I am not saying that this is good--or bad--only that this occurs very frequently. Our type of post-experimental debriefing might be criticized on ethical grounds: it helps legitimate a very questionable moral reasoning. For some subjects at least, the statement might imply that it is all right to hurt another individual (or steal or lie) if lots of others do the same thing. We obviously do not want to impart this lesson. What we are trying to do, and I think with some success, is minimize the chances that the research participants will experience a loss of self-esteem on being reminded by the investigator that they had exhibited antisocial conduct.

All post-experimental explanations obviously are not alike. Yet several studies of the effects of debriefings indicate that they can do a great deal to alleviate the unpleasant tension that might have been produced in the course of the study. Some observations recorded by Clark after his experiment with Word (1972) are fairly typical. The subjects in this study were led to hear a staged accident under various circumstances and then were watched to see if they would aid the supposed victim. Although the exact level varied somewhat with the experimental condition, about a third of the participants reported either being "very" or "mildly" upset at the time of the emergency if this emergency was unambiguous. However, when the experimental ruse was explained to them at the end of the session, "80% reported no longer being upset, 19% were still mildly upset and only 1 S indicated he was still very upset." The investigators also assessed the views of all their subjects regarding the value of this kind of research:

"The overwhelming majority of Ss (95% and 94% respectively) either agreed or strongly agreed that this type of research is valuable and that the deception practiced was unavoidable. While there was a more diverse feeling expressed concerning the ethics involved, only 2% of the Ss reported being opposed to the use of stress in psychological experiments. These findings provide evidence that the participants in these studies felt that the potential worth of the research outweighed the negative effects of the stress of deception inherent in the situation."

Berscheid and her colleagues (1973) have published similar observations. For one thing, they tell us of a study by Ring and others which essentially replicated Milgram's obedience experiment:

"After actually participating in the replication, the subjects completed a questionnaire in which their candid reactions to the experiment were solicited. Some of the subjects were given debriefing information before filling

out the questionnaire; others were not. The questionnaire was presented to the subjects as an attempt to determine 'whether any experiments in which you've participated in any way violate the rights of subjects ... '

... 4% of the Ring et al. subjects who had received debriefing information indicated that they regretted they had participated in the experiment; on a related dependent measure, 4% of the debriefed subjects indicated the experiment should not be permitted to continue. The corresponding percentages for subjects who had not received debriefing information were 43% and 57%, or, on the average, 50%. Debriefing, thus, had a substantial amelioration effect on the subjects who actually participated in this replication of the Milgram paradigm" (cited in Berscheid et al., 1973, p. 922)."

In their own investigation Berscheid and her associates provided university students with detailed descriptions of several well-known social psychological experiments, including the one by Milgram, asked them to imagine taking part in each of the studies, and then gave some of these people information about the true purpose of the described research as well as the deceptions that had been practiced. This debriefing significantly affected the students' reactions to the most stressful experiments in the series. Although the results differed somewhat from one questionnaire measure to another, the explanation given the subjects about the stressful experiments raised their reported happiness and satisfaction with themselves to the level produced by the non-stressful studies. The debriefing information had apparently countered much of the felt tension created by the stressful procedures.

These findings taken together probably reflect what post-experimental explanations can do, and not necessarily what they will do in every instance. Some investigators obviously will present a more adequate account than will others, and all of the participants will not find the explanation equally

beneficial. Still, both theory and research indicate that debriefing can lessen many of the psychological ill-effects that might have been created by the experimental procedure, including the subterfuges practiced by the researcher.

There is another point that should be raised here. As I mentioned earlier, some of the objections leveled against psychological experimentation have assumed that whatever adverse consequences result from the treatment given the participants, whether anxiety, anger or a bruised ego, might well last for a considerable period of time. An individual might not have only a brief, trivial experience when he takes part in an experiment. This is conceivable, certainly, but in the great majority of cases, I am convinced, subjects do not give the laboratory happenings much thought when they are over. The event is finished. What had taken place is usually quite unimportant to them, and they soon turn their minds to other things. The experimenter's account of the study probably helps them do this. Their behavior is translated into something that might be of interest to the investigator but is not particularly relevant to their own goals. And it does not matter much to them that the experimenter had fooled them for his own purposes.

Despite all this, some people could be hurt by their participation in the investigation. Can we predict how many will suffer and how severe their psychological injury will be? History and research say "not very well at all." Experts have made very inaccurate forecasts when they were asked to anticipate the outcome of two controversial social psychological experiments. In the first of these, at the time he conducted his research on obedience to authority,

Milgram asked psychiatrists and others to estimate the proportion of subjects who would yield to the authority's (i.e., the experimenter's) dictates and severely punish the supposedly hapless victim. Although fully 65% of the subjects obeyed their instructions and increased their punishment up to the maximum, and ostensibly dangerous, level, most of the behavioral science specialists had thought that only a small minority would do so. The members of the Stanford University Committee on Human Experimentation also failed to forecast the impact of social roles on subjects in Zimbardo's simulation of prisons (Zimbardo, Banks et al., 1973). In this latter study one group of students role-played being guards in a prison-like environment for eight hours a day over three shifts, while other men acted as the prisoners for 24 hours a day. Close observation of the participants as well as their self-reports indicated that "this simulated environment was sufficiently realistic and forceful to elicit intense, personal and often pathological reactions from the majority" (Zimbardo, 1973). As a result, the investigators terminated the experiment well before they originally intended. And yet the Stanford Committee had previously approved the research proposal because the members had not expected these strong reactions.

Let us look more closely at these two examples of the experts' failure to predict people's responses to role demands. The outside observers had not been wrong because they had given the investigator the benefit of the doubt, exhibiting a willingness to try out the experimental treatments. Rather, their theory of human behavior was in error; they had not given sufficient weight to the situational influences impinging on the participants, incorrectly assuming that the subjects would remain almost impervious to these

external forces. In this regard I agree with several other writers who have argued that some of the outcry against the Milgram and Zimbardo experiments reflects dismay at the demonstration of the power of environmental conditions over human behavior. Milgram's research probably would have been criticized much less severely if his subjects had generally resisted the authority's pressure. As Helmreich, Bakeman and Scherwitz (1973) put it:

"The upset generated by a Milgram or Zimbardo, both from the public and from their colleagues, in part stems from ethical concerns. But another part of their power lies precisely in their demonstration of how strong situational determinants are in shaping behavior ... Milgram's and Zimbardo's studies evoke public outcry in part because, through shaming demonstrations, they remind us just how fragile our ethical independence and integrity really are."

Phrasing this type of error somewhat abstractly, it appears that in their judgments the specialists had placed too much weight on internal determinants of behavior and had unduly minimized the degree to which situational factors affect conduct. Or to say this in another way, the observers had not adequately recognized the substantial variability in human behavior, the extent to which action changes from one environment to another. Walter Mischel (1968), an eminent writer on psychological assessments, has noted that expert psychologists frequently make this mistake.

This slighting of situational variability also occurs, in a sense, when people exaggerate the impact of a single event upon the individual. It is not altogether inappropriate, I believe, to regard a person as something like a shoot of bamboo. Winds (situational influences) affect the bamboo (the person) fairly easily and move it about often, first in one direction and then another. Yet the basic structure of the bamboo (the individual's personality)

is not altered so readily. In minimizing situational variability we essentially deny the individual's flexibility, the degree to which he responds frequently to environmental stimulation without undergoing a drastic and persistent change. Observers also neglect this flexibility when, as I commented earlier, they assume that one occurrence, such as a stressful treatment in a psychology experiment, will modify the subject's personality for a long time afterwards. There can be differences of opinion as to just how flexible humans ordinarily are, but I think most people are more inclined to view the personality as relatively fixed and yet fragile than as flexible and reactive but still not easily altered in any fundamental way.

The particular conception of the human personality that we employ guides our thinking about the ethical issues in behavioral research. I'll highlight what I have in mind here by referring to a research proposal that was recently made in England. A social psychologist wished to test his theoretical analysis of illegal behavior by placing teenage boys in a laboratory setting and then giving them an opportunity to steal money. The psychologist thought he would drive a van to certain working class areas of a community, recruit adolescents individually to work on an ostensible laboratory task inside the van, and then leave each boy alone with a chance to steal some cash. The youngsters would not know the actual purpose of the study or that they were actually being watched from behind a screen to see what they would do. As the psychologist noted in his proposal, this type of laboratory experimentation would yield the clearest answers to the theoretical questions he was posing and therefore might well have direct social benefits. The granting agencies he approached, however, turned him down on ethical grounds. They

seemed to be mainly afraid that the experimental experience would strengthen the teenagers' antisocial tendencies, perhaps by reinforcing their inclination to steal again in other situations. While this is a reasonable basis for concern, the psychologist who made the proposal believes the granting agencies' fears were much too strong. He thinks that most of the adolescents in his sample would have already done some stealing prior to the experiment (because of the neighborhoods from which they were recruited) so that their laboratory behavior would be, for them, just one more petty theft. He doubts whether this single experience would have had any real effect on the subjects' habitual mode of conduct.

I agree with him by and large. However, none of us can guarantee that there definitely would not be any increase in the probability of further antisocial conduct as a result of the boys' participation in the study. The granting agencies' anxiety might be excessive; maybe they assumed that, say, 10 boys in 100 would have been affected by this experience where, let us suppose, only less than one percent of the subjects would actually exhibit a heightened likelihood of more thievery. Is not that small increment still too much, especially considering the possible consequences? Do the conceivable benefits outweigh these possible costs? Who can say with any certainty?

Now let me get back to the matter of the inaccurate predictions of the outcome of the research. I have been arguing that even experts are often unable to foretell the results of many behavioral science experiments because of the uncertainties and complexities in human behavior and because their thinking about behavior frequently disregards human flexibility and

the force of situational influence. In the two examples I cited, the Milgram and Zimbardo studies, the specialists had not anticipated the controversial aspects of the research (as seen by later observers), probably partly because they had slighted situational determinants. This failure might be regarded as an error in favor of the investigators; they were, or would have been, permitted to carry out their experiments. However, human experimentation review panels are also susceptible to other kinds of errors that could act against the researcher being allowed to conduct his investigation.

What are the members of such a committee asked to do when they judge a research proposal? At times they have to assess an experimental procedure in light of fairly definite knowledge: will the subject be required to do something that is illegal (such as smoke marijuana) or that might get him into difficulty with legal authorities (for example, by admitting that he has smoked marijuana often) or that is very likely to produce physical injury (maybe by keeping his hand in ice cold water for too long a period of time)? The judgments the committee makes on the basis of this kind of knowledge rarely produce strong objections. Quarrels are much more apt to result, of course, when the review panel tries to estimate the stressfulness of a particular experimental treatment on the basis of very imperfect knowledge and little, if any, prior experience with this technique. Here the committee members have to make a behavioral prediction when the stimulus situation and the action are quite ambiguous to them.

Various biases can affect the panelists' forecasts. What is most relevant to us, I think, is the influence of the judges' set. To a very considerable extent our interpretation of an uncertain occurrence is greatly shaped by

the ideas that we happen to have in mind at the time (Bruner, 1957). Thus, if a person has been exposed to a great many threats in the past, at a later time he will be quick to interpret an ambiguous event as also threatening. If he has been insulted frequently, he will be inclined to think that an ambiguous encounter is one more insult. Behavioral scientists are not immune from these perception-distorting biases. Specialists in personality testing often exaggerate the signs of psychopathology in a test protocol (Cronbach, 1970). Psychopathology is so much in their thoughts that they may at times be overly sensitive to indications of abnormality and are too ready to interpret a strange response as a sign of serious illness. They make too much of what might actually be only a small and fairly unimportant detail.

I suggest that a similar phenomenon is apt to occur as a consequence of repeated considerations of the risks in experimental research. The more often people have to assess the possible dangers in an experimental procedure, the greater is the likelihood that ideas of threat and risk will be in their minds when they evaluate any given proposal. And as a result, they may be overly inclined to interpret an ambiguous experimental technique as a stressful one. Here too, they may make too much of something. Has this indeed happened to human experimentation review panels? If these committees are becoming increasingly cautious as they carry out their duties, is this because they have become more sensitive to the actual hazards in the proposed investigations--or have they become excessively preoccupied with ideas of danger so that they quickly interpret an ambiguous procedure as "probably risky" and then exaggerate the possible costs to the subjects?

Most discussions of the ethicality of human research have noted that the investigator might well be a biased judge of the risks inherent in his proposed study. As the Cook Committee observed in its report to the American Psychological Association:

"The investigator should not trust his own objectivity in balancing the pros and cons of going ahead with research that raises an ethical question for him. His personal involvement tends to lead him to exaggerate the scientific merit of what he is about to do and to underestimate the costs to the research participant" (Cook et al., 1973, p. 12).

Yet the investigator is by no means the only one whose judgment can be biased. Review committees can also have a tendency to err but in the opposite direction. They may not want to be unfair to the researcher and may try hard to be dispassionate in their evaluation of his planned study. They are not motivated to block his endeavors. But still, they could become overly sensitized to possible risks and see hazards that do not actually occur to the research participants simply as a result of their committee work.

Without much hard evidence, I suspect that professional ethicists are also likely to exhibit this oversensitization. In my discussions about the use of deceptions in social psychological experiments with friends at Wisconsin who are philosophers of ethics I have been impressed with the way their weighing of the costs of the research does not seem to parallel the weights employed by our student subjects. For one thing, they tend to regard misleading statements and subterfuges in research somewhat more harshly than do most of our subjects; as I noted earlier, the great majority of our subjects apparently view these deceptions as appropriate within the context of a scientific experiment. These ethicists are also inclined to see a possibly stress-

ful experimental technique as being harder on the subjects than do the subjects themselves. Once, when I made this observation to an ethicist, he suggested that the participants might feel intimidated by us, much the way poor blacks in the Deep South have resented their treatment at the hands of whites but were afraid to speak up. This analogy is quite imperfect, of course. Blacks might have been reluctant to complain directly to whites but they still expressed their feelings to each other. Psychology students do talk to each other about experiments but we have never heard that they were annoyed by the ruses and deceptions practiced on them. They occasionally complain about what they think is an excessively boring and trivial investigation, but I have not heard of student muttering about a stressful procedure that was reasonably explained to them. All in all, some aspects of social psychological experiments are evidently much more unpleasant to these particular philosophers (at least) than to the young men and women who actually serve in the studies. Ethicists are adept at analyzing the ethical issues in controversial problem situations. Nonetheless, their training and experience might also cause them to exaggerate the costs of a given experiment to the participants.

Who is in the best position to predict these costs? I do not believe that the investigator should be ruled out altogether. While his judgment could be biased, he is usually also the person with the greatest amount of experience with the research procedure in question. If he has carried out similar studies in the past with the same techniques, he is more likely than the members of the review committee to know whether his procedures actually do disturb the participants. Serious consideration should obviously be given to this knowledge. Yet his judgments of the costs and benefits can admittedly be distorted

by his personal and professional desires. The best solution, it seems to me, is to obtain reactions from observers drawn from the same population as the research participants.

Various writers have also advanced this notion. The Cook Committee of the APA implicitly argued that research evaluations should be obtained from judges who are similar to the subjects when it discussed the reason why the investigator's bias had to be corrected: The researcher "may be hindered from seeing costs from the subject's point of view, because of differences in age, economic and social background, intellectual orientation, and relationship to the project itself" (Cook et al., 1973, p. 12). As a result of his experience with his simulated prison study, Zimbardo (1973) also concluded that "students or representatives of the population being studied" should be part of the institutional committee passing on the ethics of human experimentation. Berscheid, Baron, Dermer and Libman (1973) believed that the use of representative samples would even permit evaluation committees to estimate the percentage of research participants who would object to serving in a given study:

" ... draw a sample from the proposed subject population, present it with the full procedure to be followed in the experiment along with the purpose of the experimentation and determine the extent to which these subjects would be willing to participate in the experiment described ... From this 'role-play-sampling' procedure, consent rates could be projected for the subject population" (Berscheid et al., 1973, p. 914).

I would not care to follow Berscheid's recommendation to the letter. If this strategy had to be carried out for every proposed investigation, research would become much more expensive in money, time and effort. Moreover, how can

we establish an amount and intensity of consent that would be consistent and yet reasonable for every study? Should an experiment be halted if five percent object or four percent? What if ten percent of the participant sample express misgivings but only tentatively? Is this better or worse than five percent objecting strongly? Only a rigid and expensive bureaucracy could deal consistently with these questions and the other problems that inevitably would arise if every research proposal had to be screened by a sample representing the research participants. Then too, as Berscheid and her associates recognized (1973, p. 914), their recommended procedure is open to the criticisms that have been lodged against role-playing techniques generally.

Let me digress for a moment to take up this particular matter for we have here an issue that is closely associated with the attacks on deception in psychological research. If it is ethically wrong and methodologically bad to fool subjects in an experiment, as some writers have charged, what kinds of investigations should be conducted? Kelman (1967), among others, offered an answer. The researcher should not attempt to arouse the actual attitudinal or emotional state that he wishes to study; this probably would require subterfuges. Instead, he should merely describe a situation to his research participants in which this psychological state is likely to exist and ask them how they would behave. The subjects play the role of a person in that situation rather than being actually exposed to the relevant condition. In the Berscheid procedure the participant samples are asked to play the role of someone receiving a particular treatment and then indicate how they think they would respond.

Freedman (1969) has pointed out the shortcomings in this role-playing technique. He noted, for one thing, that relatively few people care to admit they would act in a socially disapproved fashion even though many of them actually do so at times. When he describes the Milgram obedience setting to his students, none of them say they would administer the extremely severe punishment demanded by the authority and yet a majority of Milgram's subjects had complied with the authority's dictates. It amounts to this: "sometimes subjects can guess accurately how they would behave; sometimes they cannot. Any time subtle factors or interactions are involved, any time actual behavior runs counter to what is considered socially desirable or acceptable, guesses will probably tend to be wrong. But, most important, one can never know ahead of time whether the guess is right or wrong until the people are observed in the real situation ... The argument comes down to the simple truth that data from role-playing studies consist of what some group subjects guesses would be their reaction to a particular stimulus. The subjects are giving their estimates, their intuitions, their insights, and introspections about themselves or others. If we are studying the myths and values of a society, these data would be useful. If we want to know how people actually behave, they are, at best, suggestive. If we are interested in people's intuitions, fine; if we are interested in their behavior (other than guessing behavior), we must ordinarily use the experimental method" (Freedman, 1969, pp. 110-111).

Several direct comparisons of the results obtained by role playing and deception procedures have generally confirmed Freedman's observations (e.g., Willis & Willis, 1970). Sometimes people's estimates of how they would react

to a hypothetical situation faithfully mirror the behavioral of those in the actual situation; they are familiar with this type of condition, are aware of how they had responded in the past, and are not motivated to distort their reports. At other times, however, the role-playing subjects' guesses do not parallel actual behavior because they lack the requisite experience and/or awareness, or are trying to present themselves in a favorable light and this is easier to do in the role-playing than in the more spontaneous experimental situation. In sum, we cannot be sure when the guesses are right. We could not always tell whether the participant samples' reactions to the described situation accurately reflected the actual subjects' feelings.

Than chances are, nevertheless, that judges drawn from the same population as the research participants would offer better estimates of the latter's reaction to the experimental treatments than would others of a dissimilar age and background. An institutional human subjects review panel would be well-advised to obtain "input" from representatives of the population being studied. Here too, though, I would recommend a fairly frequent replacement of the panel membership. Just as those who are repeatedly engaged in assessing the risks in behavioral research might become overly inclined to see hazards in the ambiguous research settings, so might the participant-representatives become overly sensitized. With continued experience on the committee their ability to mirror the participant population faithfully therefore declines--because of their increased sophistication as well as the possible hypersensitivity to possible risks.

The thrust of my argument so far is that most criticisms of the ethicality of human experimentation in the behavioral sciences are based on exaggerated fears. This does not mean that it is not necessary to obtain the informed consent of the research participants before they are exposed to the investigation. Together with practically every other behavioral researcher, I subscribe to the statement made by the Cook Committee:

"The psychologist's ethical obligation to use people as research participants only if they give their informed consent rests on well-established traditions of research ethics and on strong rational grounds. The individual's human right of free choice requires that his decision to participate may be made in the light of adequate and accurate information" (Cook et al., 1973, p. 27).

The question is, what kind of information should be provided? As the APA committee observed, "Ethical problems arise because the requirements of effective psychological research often conflict with the simple fulfillment of this obligation to obtain informed consent." How can this conflict be resolved? Indeed, is there any definite solution?

Let us begin this discussion with the time the investigator first encounters the research participants. The initial question is whether the researcher is obligated to inform his subjects that he is studying them. There is little problem here (for our present purposes) when the participants are volunteers. They know they are in an investigation. However, what if the researcher wants to observe people in naturalistic settings? Does he have to tell them of his interest and purposes? As the Cook Committee observed, "the boundary between drawing legitimately on one's everyday experience and spying is a narrow one. Some critics feel that the investigator who invades private situations under false pretences or with concealed observation is entirely out of bounds; others

feel that there are problems and circumstances in regard to which it may be warranted" (p. 32). I am in this latter group.

Suppose a sociologist was interested in the interactions among guests at cocktail parties. Let us say that he simply recorded his general impressions after each party he attended and then pulled his observations together sometime later in an overall report. None of the guests can be identified in this report. In this case I would say that the investigator is not ethically bound to announce his research intentions every time he goes to a party. Requiring him to declare his purposes would also mean that every writer should proclaim his professional role whenever he met other people. The writer, like our sociologist, stores his impressions in his memory and then employs these recollections in one way or another in a later story, article or book. A novelist is basically no different from a sociologist in this regard even if the latter tallied the frequency of certain acts and the novelist only formed vague judgments of how frequently something was done. Both seek to portray an aspect of social reality. Nor does it matter, I believe, what their intentions were when they entered a social situation. A writer, whether he makes up stories or conveys a group's ideas, sooner or later will use his experiences in some fashion in his work. It may be the experiences of the moment if they strike his fancy or seem important to him. And continuing in the same vein, I do not think we can differentiate between the sociologist and the writer when the portraits they draw are unfavorable to a particular group. A novelist does not have to identify himself to those he meets even if he will eventually satirize their way of life, and the sociologist

does not have to say what he is doing although his report may have negative things to say about people who go to cocktail parties.

Neither the present sociologist or novelist manipulate anything in the course of their observations. The problem becomes somewhat more complicated when the investigation produces a substantial variation in the lives of the participants. Sometimes this is unintended, but at other times the alteration may be deliberate, as when a field experiment is conducted. The book "When Prophecy Fails," by Festinger, Schachter and Riecken illustrates the complexities in the former type of research. In order to test their analysis of what happens after a failure to confirm a strongly held belief, the investigators sent several participant observers to join a group of persons in a nearby community who predicted that the city would soon be inundated by a flood. Needless to say, the catastrophe did not occur and the observers recorded the group reactions. When the report was published the research was criticized by at least one behavioral scientist (Smith) on ethical grounds; by introducing other persons into the group who pretended they believed the flood prediction, the researchers might have helped support the group's belief. They therefore presumably exposed the members to a somewhat greater shock when the expectation was not confirmed. Well, I cannot say that I share the critic's misgivings in this case. The group members were in danger of scorn and disapproval even without the extra support introduced by the research team. Further, the critic's point could question a good many participant-observation studies. From my perspective the gains that might result from this kind of research often outweigh the slight increment in costs produced by this type of unintentional variation.

But what about deliberate manipulations of the attitudes and feelings of people who do not know they are in an experiment? The experiment of Piliavin, Rodin and Piliavin (1969) is a good example. These researchers wanted to investigate some of the conditions affecting the willingness to aid a person in distress. Pursuing this aim, they staged a series of accidents in a New York subway car, varying the race of the victim (white or black) and whether he appeared to be drunk or a cripple. Certain naturally occurring variations were also examined, such as the number of onlookers in the car. More and more field experiments such as this one are being conducted in social psychology, covering an ever wider range of research questions and settings. I view most of these studies as legitimate enterprises. Although, it is true that the research participants are being manipulated by the investigators, they (a) are confronted by the kind of situation that could easily occur naturally in their environment, and do not realize that their attitudes are being operated upon. Moreover, (b) the ultimate goals of this research are socially quite defensible.

These two points are fairly important, I believe. The first one means that the participants will not have a feeling of being pushed around and will have no reason to believe that their individual autonomy and dignity have been violated. For them, they are only facing the kind of life situation they might normally encounter and their habitual modes of adaptation can readily deal with whatever happens. They therefore should not suffer any loss of self-esteem. No matter what they do, whether they help or do not aid the victim in a Piliavin-type situation, their customary ways of thinking will tend to justify their action, and there is little likelihood that

they will be substantially affected. However, the research participants are actually being manipulated, of course, and my second point is that the social benefits that derive from the accumulation and dissemination of scientific knowledge about human behavior are greater than this relatively small cost.

My argument, then, is that the people involved in most field experiments do not have to be told that they are taking part in a study. This is also scientifically desirable. Informing them beforehand of the experiment is very likely to produce a Hawthorne Effect. Many persons alter their conduct when they think they are being watched, even if the observers are researchers. They want to look good, gain the approval of the onlookers, and so they are particularly apt to do the "right thing." Consequently, their behavior may not be representative of how they would normally act in this "real world" setting. The advantages of the field experiment are therefore lost to the investigator.

This reasoning obviously has implications for the debriefing procedure. I suggest that if the participants do not realize they are in an experiment, it is ordinarily unnecessary--and may even be undesirable--to let them know afterwards what had actually happened. My contention is that the staged event will probably have only a fleeting impact on the subjects because their ordinary defenses and ways of thinking enable them to adopt readily to the occurrence. These defenses are directly confronted when the experimenter reveals what he had done to the participants. Consider the subway riders in the Piliavin et al. study. How would they feel if the investiga-

tors had explained their purposes? Those subjects who had aided the "victim" might be pleased, of course; they had behaved in a socially approved fashion. But, on the other hand, what about those who had not been helpful? By talking about the experiment, the researchers essentially tell these persons that they had not acted properly. Their self-esteem could then suffer.

The reader might ask at this time, what is the difference between these particular research participants and the subjects in a university psychology experiment? Suppose the main features of the Piliavin study had been established under the laboratory conditions (and this has actually been done many times), and a subject fails to assist the individual in need. Would he not also experience a blow to his ego at learning afterwards that he had not acted in a socially responsible manner? How can we justify the post-experimental explanation for him, and even say that this explanation is obligatory, while recommending no debriefing for those taking part in most field experiments?

The major difference, it seems to me, is that the laboratory subject knows he has responded to some experimental treatment. He is owed at least an account of the investigation in order to justify whatever coercion or pressure he felt in taking part in the study and to lessen whatever stress he might have experienced. The debriefing might not eliminate the ill-effects of the experiment altogether. There might even be a small chance that the researcher's revelation will wound the subject by pointing up his "bad" or undesirable behavior. Yet we should take this risk in order to help restore his sense of autonomy. If the research participants had not lost this feeling of independence, it is not necessary to expose them to the possible hazards

of the post-experimental explanation. They do not have to regain something they have not lost.

Of course, there are times when the participants in field experiments should be given the same kind of careful debriefing provided to the laboratory subjects. In general, this is when there is some kind of indication that the participants had been upset, disturbed or otherwise emotionally aroused by the experimental procedure. There are very complex considerations and I believe this section is best concluded with some comments made by the APA's Cook Committee:

"When the man in the street becomes an unwitting participant in research, realism has been combined with experimental control, but sometimes at considerable ethical cost. Informed consent is impossible. In the least questionable cases neither the anonymity nor the personal dignity of the participant is violated, and patience is only trivially imposed upon. But offenses to human dignity are readily imaginable in this sort of experimentation. As such procedures become more numerous in an effort to obtain information about important social issues, there is reason to fear their cumulative effect ... such research can be considered only with misgivings" (Cook et al., 1973, p. 33).

Moving on to consider another aspect of the investigator's dealings with the research participants, we now come, finally, to the matter of information about people's discomforts. Virtually everyone is agreed that it is desirable to tell the potential subjects what will happen to them at the time their cooperation is being solicited. They should know what they will be getting into. HEW regulations stipulate that informed consent requires "a description of any attendant discomforts and risks reasonably to be expected," while the APA list of ethical principles includes this statement:

"Ethical practice requires the investigator to inform the participant of all features of the research that reasonably might be expected to influence willingness to participate ... " (Cook et al., 1973, p. 29).

Here too, however, a conflict can arise between this very reasonable, easily understandable principle and the scientific requirements of the research.

One problem is that the potential participants might be frightened unduly. In another background paper to the National Commission, Robert J. Levine cites an experiment by Epstein and Lasagna which documents some of the perils of overdisclosure:

"They presented consent forms of various lengths and thoroughness to prospective subjects of a drug study. They found that the more detail was included the more likely were the prospective subjects to be either confused or intimidated" (pp. 17-18).

Could it be that the great emphasis on the possible ill-effects of the drug produced the same kind of overweighing of conceivable dangers that I discussed earlier? Just as personality testers sometimes give excessive attention to faint signs of psychopathology in a test protocol, the Epstein and Lasagna subjects might have exaggerated the hazards in taking the drug because their attention was focused almost exclusively on these possible risks. In much the same way, a behavioral scientist could arouse much too much anxiety in his potential subjects by over emphasizing the conceivable sources of discomfort in his investigation. By enumerating everything that might possibly go wrong, he causes them to "accentuate the negative."

Another problem (from the researcher's perspective) is that complete information about every possible source of unhappiness could lessen the effectiveness of the experimental treatment. If the prospective participant was

told about every feature of the research that might influence his willingness to participate, it would be difficult (if not even impossible) to carry out some kinds of experiments. Researchers would probably be unable to examine experimentally the consequences of anger or anxiety arousal. Following the APA's ethical principle to the letter, the potential subjects would have to be informed that, say, they might be frightened (or upset or emotionally aroused) in the course of the study. After all, this information could "reasonably" affect their willingness to be in the investigation. But obviously, if the subjects had this knowledge and agreed to participate, it would be exceedingly difficult to create the appropriate feelings within them. Being forewarned, they are forearmed against the experimental treatment.

In my view this particular principle should serve as a general guideline rather than as a strict rule. The Cook Committee clearly recognized this. After presenting the principle we are now discussing, this committee then went on to say:

"When the methodological requirements of a study necessitate concealment or deception, the investigator is required to ensure the participant's understanding of the reasons for this action ... " (p. 29).

In other words, the post-experimental debriefing could compensate considerably for the lack of full disclosure at the time the subject's consent is obtained.

From where I stand an appropriate compromise is to explicitly mention each possible source of physical discomfort (e.g., that electric shocks may be employed in the study) when the pre-experimental information is given, but not say anything at this time about the psychological manipulations

that will be carried out. However, and I think this is exceedingly important, the investigator should also emphasize that the subject is free to withdraw from the study at any time he wishes with full payment or credit and without jeopardizing his relationship with the researcher or institution.

The reader's values obviously will determine his reaction to this kind of compromise or, for that matter, his response to the general trend of comments in this paper. By and large, those with a strong humanistic orientation will be especially repelled by the idea that our research participants are often exposed to psychological stresses or even that the subjects' attitudes and feelings are being manipulated without their fully informed consent. I do not mean to question the desire to preserve individual dignity and autonomy. I do believe, nevertheless, that the advance of behavioral science can contribute to the preservation and strengthening of these values. People are being manipulated every day by forces outside of their control and often to their personal detriment. The development and dissemination of behavioral science knowledge can lead to a greater awareness of these influences and the steps that might be taken to counteract them. A sound behavioral science can help uncover the truth about determinants of human conduct, and as in other domains of life, the truth can make us free.

SELECTED ISSUES IN INFORMED CONSENT AND CONFIDENTIALITY
WITH SPECIAL REFERENCE TO BEHAVIORAL/SOCIAL
SCIENCE RESEARCH/INQUIRY

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I. INTRODUCTION

This essay explores what Edward Shils calls the confrontation of autonomy and privacy by a free intellectual curiosity (1959:121). It does so by examining how institutions of consent and confidentiality are organized in behavioral science inquiry. Their role in regulating the acquisition, processing, and dissemination of knowledge is its major concern. Regulations instituted by the Federal Government for implementation by agents who sponsor or undertake sponsored inquiry are reviewed for the issues they present for behavioral science inquiry. Special attention is given to analyzing the Code of Federal Regulations for the protection of human subjects in research, development, and related activities supported by Department of Health, Education, and Welfare grants and contracts (45 CFR 46), the proposed code of regulations governing the confidentiality of individually identifiable research and statistical information collected under Law Enforcement Assistance grant programs (28 CFR 22), and the proposed code of regulations to protect the privacy of research subjects by withholding from all persons not connected with the research the names and other identifying characteristics of such subjects in research on mental health sponsored by the Department of Health, Education, and Welfare (42 CFR 2a).

The Problem Setting

The behavioral scientist's access to information is limited by important proprietary rights in information and individual and collective rights to secrecy and privacy. Governments assert rights to keep secret or confidential information to protect national security and the deliberative processes of executive, legislative, and judicial agencies, and information on individuals or collectivities to which it is privy to insure their privacy and

protect their proprietary rights. Corporations and other collectivites such as professions and voluntary bodies have legally guaranteed proprietary rights to information to protect the autonomy of the organization and their clients' right to privacy. There are, similarly, proprietary interests for private persons and a right to security of private personal expression and affairs (Warren and Brandeis, 1890; Pound, 1915:343).

In a free and open society, these proprietary interests and private rights confront public rights and claims to information. What is available in the public interest depends upon both law and custom, including the customs of a scholarly community, and its interpretation in any given case as to what is public and what is privileged. The federal Privacy Act and the Freedom of Information Act among others define rights and privileges in information and access to information.

The behavioral scientist's access to information is normatively a matter of right to information that is public and a matter of consent where it is proprietary, private, or privileged.¹ How to regulate the acquisition, processing, and dissemination of information is especially problematic in a free and open society. At the present time regulation is in a state of flux. Some recent federal and state laws make the information of public bodies more accessible to inquiry while at the same time information for private organizations and persons is subject to more legal, ethical, and organizational regulation to protect proprietary rights in information and corporate and individual rights to privacy. The customary fiducial relationship of scientific investigators and their sources of information is both subject to growing regulation in the interest of protecting the rights and integrity of those sources and jeopardy by the inability of investigators to resist efforts to break confidences or to control their misuse. Tradi-

tionally investigators guaranteed their sources of information the protection of confidentiality but the growth of legal challenges to their right to confidentiality threatens the foundation of their fiducial obligation. In what follows some issues and problems in obtaining information through a fiducial relationship of consent and confidentiality are explored and ethical, legal, and organizational forms of regulation to protect proprietary rights in information, corporate and individual rights to privacy, and the privileges of investigators in behavioral science research are examined. Both trust and privilege are paradoxically elements in maintaining scientific inquiry in a free and open society.

Right to Privacy

The "right to individual privacy" has its roots in the common law (Warren and Brandeis, 1890) and it has gradually been extended to corporate bodies in one form or another. The "right to privacy" is a complex legal concept embracing several related concerns such as the right of individuals (1) to be "left alone," (2) to be secure from intrusion into private affairs by unwarranted means, and (3) to be secure against unauthorized entry into one's domicile or private place. The right extends also to proprietary interests in intellectual property such as trade secrets, original work subject to patent or copyright, and the like. Each of these rights may be intruded upon by behavioral science inquiry. Transgressions are not easily defined or recognized. Worth pondering are questions such as these: (1) is the entry of a research observer with a police officer into the domicile of a private citizen a "lawful entry"? (2) is the recording of a public meeting, including such 'private conversations' as may take place during the meeting, an intrusion by unwarranted means? (3) is privacy respected when one has

the consent of an employer to secure information from the personnel records before information on identity of the employee is removed?

At law, the privacy of another is invaded when there is an unreasonable interference in making public any affairs that a person wishes to remain private. A social research investigator invades privacy when he is responsible for public disclosure of private facts or when such public disclosure puts another in a derogatory light before the public (Goldstein, 1969:423). A proposed revision of the law of torts prepared by the American Law Institute broadens considerably the concept of invasion of privacy to include " . . . one who intentionally intrudes physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns . . . if the intrusion would be highly offensive to a reasonable man" (1969:418). As Nejelski and Lerman note (1971:1126) intrusion upon solitude may occur when social scientists make unobtrusive observations and the identity of those observed becomes known. Whenever consent is lacking as an element in securing information on private matters, the investigator risks invading the privacy of others, even when that information is secured in public settings. Much may depend, of course, on the capacity of investigators to keep private information from becoming public knowledge.

In much, though not all, behavioral science research, there is some intrusion upon the privacy of others, seem it ever so slight. Apart from the fact that research investigators have a legal liability to suit for invasion of privacy, ethical values constrain the intrusion upon privacy without recourse to consent or some appeal to a priority of values. We shall briefly examine below some of the principal criteria invoked to justify intrusion into private affairs.

The typical criterion invoked is that intrusion on privacy is justified

in the interest of developing new knowledge or scientific knowledge. The criterion of "developing new knowledge" is of little utility since all knowledge is in some sense "new." Perhaps one is on somewhat firmer grounds invoking the criterion of contribution to "scientific knowledge." Ordinarily to qualify as scientific knowledge, the study design should meet at least minimal criteria of scientific method. The criterion of scientific or methodological merit of the research design may be unduly restrictive on scientific exploration, however. Much exploratory social research, particularly that by participant observation, might fail by methodological criteria. The issue as to whether exploratory research into private matters is justifiable, absent a formal design of scientific merit, merits careful consideration.

Apart from the simple intrusion into the seclusion of others, intrusion occurs in obtaining information on the private matters of specific identifiable individuals. The degree to which the investigator designs instruments that define in advance these private matters affects the extent to which one can test whether the intrusion is warranted in the interest of new or scientific knowledge. The more unplanned and diffuse the intrusion into private matters, the more one is likely to probe for additional information; and, the more one searches for the "confidential," the more likely one is to intrude upon matters that are purely personal and private and perhaps more potentially damaging to subjects or corporate bodies.² That behavioral scientists may deliberately search for the "hidden agenda," the "latent attitudes," the evidence for deviance or corruption is clear from many studies. The responsibility for utilizing techniques of investigation that deliberately search for these intrusions is not commonly dealt with in reports of such intrusions; yet they merit careful consideration.

Where the intrusion is planned, careful consideration must be given to the trade-offs between the relative degree and cost of intrusion into the privacy of others and the gains from it. On what grounds does one justify questions about drug use, for whom one voted in the last election, or one's income? What will happen to the response rate if just prior to asking the question one advises the respondent of freedom not to answer the question? How much of a "no response" or refusal rate, or of what is called error in reporting, stems from the respondent's belief that it is a private matter and of no concern to the investigator? These seem like questions worth answering if one is to intrude upon the privacy of others. At the present time judgments about the relative privacy of matters cannot be scaled precisely and compared with judgments about the net worth of gaining that information. Yet whether one uses the legal criterion of objectionable to a "reasonable man" or an empirical criterion such as the percent of subjects objecting to the asking of, or responding to, a particular question, differences in the relative privacy of matters are determinable. The determination of the net worth of undertaking a particular investigation may be a more difficult task, though such judgments are commonly made in rating research proposals for financial support. What remains problematic, however, for those who advance this criterion, is what criteria shall govern decisions to undertake research once the cost of intrusion into privacy and the net worth of the knowledge have been established.

Alternatively, some investigators invoke the criterion that intrusion on privacy is justified when the knowledge is necessary to matters of public importance or interest. One is justified, for example, in asking questions about birth control, abortions, and unwanted pregnancies as essential to the formation of population policies. A difficulty with this criterion is that

so long as an investigator determines what is in the public interest, there can be obvious contamination of judgment. In any case, there again are no clear decision criteria for making judgments based on relating the relative public importance of matters to the relative costs of intruding into private matters.

Consent. The criterion most commonly invoked by scientists to intrude upon privacy is that intrusion into private matters is justified for scientific inquiry when consent is secured for access to these matters. Clarification of this criterion raises questions about who shall secure consent from whom, how, and with what anticipated consequences from participation. The institutional doctrine that derives from an answer to these questions is that of informed consent. Consent " . . . concerns the conditions under which information is obtained from a person" (Ruebhausen and Brim, 1965:1197); it is an affirmative agreement by free choice to provide information under stated or agreed upon conditions. For consent to be informed means that anyone consenting must be able to predict reasonably well from a description of the procedure to be used in acquiring information and from such other information as is provided what information will be sought and what risks or benefits will follow from participation, given only the information provided at the time consent is initially requested. Formally, informed consent is an agreement that satisfies the conditions of an enforceable contract. The definition of informed consent currently operative in the regulations that are applicable to all Department of Health, Education, and Welfare grants and contracts supporting research, development, and related activities in which human subjects are involved follows (45 CFR 46.3):

"Informed consent" means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or any other form of con-

straint or coercion. The basic elements of information necessary to such consent are:

(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

(2) a description of any attendant discomforts and risks reasonably to be expected;

(3) a description of any benefits reasonably to be expected;

(4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) an offer to answer any inquiries concerning the procedures; and

(6) an instruction that the person is free to withdraw his consent and to discontinue participation in the project at any time without prejudice to the subject.

Each of these elements of informed consent is examined in Section II below, particularly as each bears upon behavioral science research.

Confidentiality. Issues in informed consent in behavior science research cannot be discussed fully without reference to the question of the private or confidential nature of much information and its protection. Confidentiality refers to " . . . the conditions under which the information is used." (Ruebhausen and Brim, 1965:1197); it involves an obligation to keep private matters confidential and free from public disclosure unless there is consent from the private party to do so or some overriding collective interest to make such matters public. There are other reasons, however, why the matter of informed consent is inextricably interwoven with the confidentiality of information and its protection.

First, an element in informed consent is to apprise the party from whom consent is sought of any risks involved from participation in the research. It is commonly the case in behavioral science inquiry that there is little harm in the procedure for acquiring information but that when harm arises it does so from the public disclosure of private or confidential matters that were communicated as a confidence. A fiducial relationship is at stake. Once an investigator acquires any information for social research that can

cause harm, as a party to that information, he is potentially an agent for doing harm. Where protection of confidential information cannot reasonably be guaranteed, an element in informed consent should be to advise that there is some risk of disclosure provided there is no adequate legal protection.

It indeed can be argued that to provide adequate protection in behavioral science inquiry where information is acquired on private matters and there is no legal protection or sanctions against compelled or unauthorized disclosure, it should be mandatory to inform the person from whom information is sought in a manner akin to that of a Miranda warning: "I must advise you that you have a right to refuse to participate or to answer any query put to you since anything you say or do can cause you harm for I cannot legally protect any of the information that you disclose to me, including the fact that you were a participant in this study."

Second, there are risks even for the parties who refuse to participate in a particular behavioral science or bio-medical study should the investigator be legally compelled to publically disclose that fact of refusal or if it otherwise becomes public knowledge. Consider making public a list of persons who refused to participate in a study of "former patients in a drug addiction center," a study of "homosexual networks," or a project studying "persons discharged by their employer." Might not such disclosure cause considerable damage to reputation and substantially risk future opportunities and benefits as well for those who refused? A particularly thorny problem thus is raised about approaching persons for their consent when even the knowledge of that approach is potentially harmful. No Miranda type warning will suffice in such a situation. Where confidentiality is at issue, any protection of informed consent is insufficient when public disclosure of refusal is harmful.

Third, where confidentiality must be maintained to protect the parties

from whom information is obtained, the requirement that one advise of the risks that might reasonably be expected may prove unusually burdensome. This is so for a number of related reasons. Often one lacks sufficient knowledge about subjects and what might prove damaging to them on disclosure. Although persons have a right to refuse information, if they have not done so, it may be a consequence of their difficulty in predicting the consequences of that disclosure--particularly in the prototype situations for eliciting information in behavioral science inquiry. Investigators often lack information on how the information they seek might easily turn out to be harmful, since there is no established knowledge in the matter and they are far from omnipotent. Moreover, whether individuals or collectivities are the object of inquiry, particular outcomes cannot be promised in many instances with any high degree of validity and reliability. At best one often makes only an "informed guess."

Finally, behavioral science research occurs in diverse settings that are at best characterized as "uncontrolled" research settings. Investigators or their agents often must enter settings over which they have little direct control and usually limited indirect control. Indeed, often they may enter a private place where others are present and the rounds of social life go on. As a result of being admitted to private places or as an unintended consequence of a research procedure, information often is acquired that was not intended as part of the designed inquiry. That such information could be potentially harmful to the person who granted consent for a particular study is quite obvious. That the investigator often may not have wanted to become privy to the matter should be equally obvious. Yet to leave unprotected all information that is acquired apart from the research design set forth in securing informed consent is to increase the risk of harm to any participant

in a research project. Parenthetically, one might note that to leave unprotected the private utterances of patients being observed for post-operative procedure may similarly increase their risk. Unless what one becomes party to in a research role is, with few exceptions such as the commission of a heinous crime, protected, informed consent should include the advice that anything that is unrelated to the research inquiry which is said or that occurs in the presence of the (outside) investigator can be used against them. The dilemma this creates for all parties to the research should be clear, but it is particularly critical for the informants or participants. Unable to either forecast what will be covered by the research design or to fully comprehend that which is and is not in a particular instance covered by the research mandate, the best advice one should give prospective participants perhaps is to refuse to participate if for any reason the participant expects that any confidential information will be secured that may be harmful. But, in any case all parties should be aware of the fact that others who are not connected with the research process may decide what was not part of the inquiry and that all parties are unprotected in such matters. Without protection for confidential or private matters that are acquired apart from the intent of the research then, investigators should not only make judgments about the likelihood potentially damaging information might be acquired through their particular design or from the nature of their research settings but in any case they should advise parties they are so unprotected.

There is inevitably some risk that investigators may take undue advantage of any protection for all information secured from and about parties to a research inquiry. They may, for instance, use it for unauthorized inquiry. Such possibilities exist, but they seem hardly an argument for

leaving participants unprotected, particularly when they often do not volunteer for research but are approached for their participation.

For these reasons then, we consider both separately and together matters of consent and confidentiality and their regulation. Before doing so we shall consider the main model that underlies the regulation of research by the Department of Health, Education, and Welfare.

The Human Subject Model. Much of the writing on regulating the acquisition, processing, and dissemination of knowledge is based on an elementary model of a principal investigator--commonly referred to as PI--acting upon or intervening in the life of a subject--commonly referred to as S. We shall speak of this as the Human Subject Model; it is the prototype in regulating bio-medical research. Our interest in this model here lies in the fact that it also underlies the Code of Federal Regulations for research grants and contracts of the Department of Health, Education, and Welfare that might be undertaken by behavioral scientists (45 CFR 46). Although understanding this elementary model is useful in articulating other models of inquiry, it oversimplifies problems and issues in informed consent and confidentiality in behavioral science investigations and for that matter, much bio-medical research as well. The Human Subject model of research is an oversimplification for stating rules to protect human subjects and maintain free inquiry for a number of reasons.

Much research is undertaken by a team or organization where a fairly large number of employees as well as investigators acquire and have access to information regarded as confidential. The principal investigator often may acquire none of the data, relying upon others to do so, and often operates primarily in the roles of administrator of the research and principal analyst. Frequently in social research, moreover, the object of the inquiry is an

integral social group, organization, or collectivity rather than a person as subject. Confidential information frequently is obtained by indirect rather than direct inquiry or from confidential records (Goldstein, 1969: 417-37). Consent for access to confidential information may be sought from administrators of records or from parties other than those who are the original source of information. A growing number of studies depend upon systematic observation of natural social phenomena where the consent of the observed is not regarded as problematic. Visual and audio methods of acquiring and storing information and computer storage and processing both facilitate and complicate problems of identification and access to information.

Suffice it to say then, that the roles and parties to research do not conform to the elementary model of a one-to-one investigator and subject relationship. The prototype model for behavioral science research perhaps is the sample survey. In the sample survey sampling statisticians select addresses of respondents who are then approached for interview by persons who are not subject to immediate supervision. The work product of interviewers is reviewed by a supervisor who may also make direct inquiry of the respondents to verify information and audit interviewer conduct. This information in turn is transmitted to a field office where confidential information may be processed by coders and analysts before identification is removed. Still others will prepare the data for computation and analysis in a chain that ends with the preparation and dissemination of research reports. Some, if not all, of these specialists may need to have access to confidential information that identifies private parties. Few respondents in a survey who consent to participate by being interviewed could readily comprehend or become aware of this chain of accessibility to their confidence.

That principal investigators can guarantee confidentiality under these circumstances is open to question. What is remarkable perhaps is how little evidence there is that such trust and confidence is misused or broken.

Other models exist in behavioral science research where the Human Subject model is a gross oversimplification. Some of these are considered later such as that for the systematic observation of behavior patterns and interactions, the study of organizational behavior--including organizational processes of regulation--, and the quasi-experiment in natural social settings. Without explicating each of these models here, we simply ask the reader to bear in mind that some of the issues and problems that arise in applying current federal regulations of behavioral science research derive from their conceptualization in terms of the elementary Human Subject model.

II. INFORMED CONSENT

Informed consent is said to involve " . . . the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion" (45 CFR 46.3).

Conditions of Consent. A strict construction of this definition would make it mandatory for any Institutional Review Board to decline approval for any proposal where there is either any "undue inducement . . . or other form of constraint . . ." or "any element (*italics mine*) of force, fraud, deceit, duress, or other form of . . . coercion." From a behavioral science perspective many research studies could not qualify for approval under a strict construction

We shall try to explain why this is so.

Criterion of Undue Inducements. At issue in the matter of undue inducements is whether inducements have an effect on choice so as to make it "not free." To a behavioral scientist, of course, this is in itself an empirical question rather than a matter of "informed judgment" and it is well recognized that each of the terms--undue, inducement, free, and choice--can be operationalized in different ways for scientific investigation. Just when inducements become an "undue" element influencing choice would probably not be altogether evident in any empirical investigation of the relationships between inducements and choice. Consider but one example, the question of whether and when subject payments for participation in an experiment or other scientific investigation constitute an "undue inducement." One would expect that members of a population would vary considerably in whether a given payment had a substantial effect on inducing them to participate. Perhaps the poorer one is, the more likely one is to opt for a given payment when one would otherwise have refused. The very young, the very old, and the unemployed may be more susceptible to any sum becoming a sufficient inducement to bring participation. Yet the matter is complicated and difficult to measure. For a good many kinds of behavioral science studies most people, most of the time, will participate when there is only a simple request to do so and at the conclusion of the inquiry will express satisfaction in having done so. It will take a complex design to ferret out the willingness to participate in a given kind of research without any inducement--whatever that might be--and their willingness to participate only under a given level of inducement. To substitute judgment for empirical inquiry in such matters seems a dubious requirement since it will tend to lead to conventions about inducements that are false, with errors in both directions.

That is, some inducements will be tabooed on grounds that they are "undue" when in fact they are not while others will be approved as not being "undue," when in fact they are. Moreover, under a strict construction, one is barred from examining the question of the effect of inducements on choice to participate in a given kind of scientific study, since one is prohibited from offering "undue inducements": they are mala prohibita if not mala in se.

Money is only one class of inducements that might have an effect on choice. There are many other forms of inducement or reward that vary in the extent to which their effects are definable and measurable. Prestige, offers of feedback concerning skills or personality, and opportunities to develop skills or secure new information can be forms of inducement that at least for some subjects may unduly influence their choice.

The form of inducements can be subtle and indirect, particularly when peer or group interests and pressures combine in a consent procedure. A simple example may illustrate some dilemmas and contradictions in approving a consent procedure. Consider the approval of an experiment of the effects of inducements on the rate of learning. The experiment provides for both individual and aggregate rewards for increments in the rate of learning. The consent of parents must be secured for the student to participate in the experiment. The school administration prefers that all students participate in the experiment as does the investigator. It is more costly to contact the parents directly than to do so via their children, so the latter mode of contact for seeking consent is approved. Moreover, it is fairly well known that the rate of return of consent forms is affected by factors other than the willingness of the parent to grant consent. Thus a procedure is approved whereby the parent is asked to sign the form only if they disapprove of participation (an approved modification of the written consent provision).

Apart from questions about whether this procedure balances consent unduly in favor of the sponsors of the research, which it well might, other indirect inducements may be operating. Suppose one's peers encourage participation in the study--even added to the proffered inducements, the study, for example, provides an opportunity to be free of the daily routine. Under the approved procedure, some students would never show the form to their parents or, if the consent of both parents is not required, select the parent who is most amenable to their persuasion. Moreover, most parents may well sign without a careful reading; they succumb in the moment to the request for a signature--"you've got to sign this, so I can take this test." Indeed, only empirical inquiry can shed light on how parent consent procedures work. We know very little about them, if for no other reason than that the behavioral science community, like any community, may opt for "functional ignorance." Unless approval is forthcoming for studying the effect of inducements on consent and unless review boards are vigilant in searching for indirect as well as direct forms of inducement, considerable "error" will attend the decisions about inducements.

Criterion of Coercion: Force, Fraud, Deceit, Duress. Institutional Review Boards are required under the strict construction to disapprove any research project where there is any element of coercion by force, fraud, deceit, duress, or other means. Except for research designs that require deception in soliciting consent, the direct use of force, fraud, or duress by investigators in soliciting consent is uncommon. There are, however, somewhat more studies where force or duress is an element that may affect the continuing grant of consent during the inquiry by applying pressure against withdrawal. Again such forms of force and duress are less likely to be direct manipulations by investigators than consequences of the procedure or of the

very phenomenon that is under investigation. The Milgram () and Zimbardo () experiments are but obvious examples of such elements operating before and during the inquiry because the elements of coercion and duress were themselves objects of investigation.

Yet it is the less obvious sources that pose difficulty for Institutional Review Boards in behavioral science inquiry, particularly if one is careful to insure that there is freedom not only to enter the research relationship but to refuse to respond to specific inquiries for information and to terminate at any time the relationship altogether. These may very well be stages in processes of social engagement and disengagement. Once committed by the initial consent procedure, fiducial relationships are not easily broken. A person may prefer deliberate deceit in reply over a refusal to answer or termination of consent--an interesting moral dilemma--or one may give truthful answers that would not be given were it not for the "threshold problems" in breaking a fiducial relationship.

It is reasonably well established that groups have considerable power over their membership by legitimating forms of coercion or duress. These very elements may be incorporated as features in a study design, either procedurally or as objects of inquiry. A few examples may illustrate the kinds of decision problems that might arise for Institutional Review Boards:

(1) Using Group Techniques. Many forms of group therapy or change depend upon group processes where force and duress are elements of group process. Such techniques are also used simply to acquire information on group processes. Coercive pressures from the group to continue in the face of any member's wish to withdraw are particularly common. They are more evident, for example, in the use of Tavistock than NTL group techniques but often arise in group settings as a consequence of the procedural mode of

inquiry or the study design. Even where the procedure is described in advance, and consent is given, the experience under group pressure may have a substantial effect on the choice to withdraw.

(2) Using Contract to Secure Information. While the elements of contract may be present in many consent procedures, e.g., paying subjects to participate or offering some other benefit directly to the participant, under certain circumstances formal contract is an element in behavioral science research. This is not uncommonly the case in evaluation research of government programs where federal legislation and policy makes funding contingent upon agreement to outside evaluation. Under these conditions the choice to withdraw is constrained by formal contract and indeed the cost of doing so may be coercive in continuing participation. Employees of programs being evaluated may similarly contract for participation in the evaluation as a condition of employment in the program. Where formal contract governs requirements for participation, the element of free choice to participate and withdraw may inevitably be compromised. The need to evaluate federal programs given their costs and consequences may be deemed compelling in the resort to contract. Perhaps some guidelines for the use of formal contract for organizations and their agents is necessary to guide the discretionary choices of Institutional Review Boards.

(3) Using Organizational Sponsorship and Participation. Parties providing information on private matters or in their organizational roles--as officials, clients, agents, or employees--must be given to understand that their failure to participate in no way jeopardizes them or their affiliative relationship. The condition is not easily satisfied. Is there no element of coercion when students in courses are asked to participate in research? when anyone superior in a hierarchy of authority asks an inferior

to participate? when an organizational decision or formal agreement to participate precedes the request for consent from individual participants? Whenever an organization stands to benefit from feedback generated in a behavioral science inquiry, it has an incentive to agree to and encourage participation from its members. When is encouragement not coercion?

Equally important to the understanding of the effects of organizational power on member participation, is the question of whether there are ways of eliminating all effects of organizational power. It seems possible to reduce such effects when present but their elimination, as the strict construction implies, seems doubtful. Thus, while I know of ways that I can minimize the effects of teacher power over students and still have them participate in teacher sponsored research, in each case there is still the possibility that residual elements of coercion exist.

Apart from the direct effect of organizational sponsorship and participation on the consent of members, there may be indirect effects of organizational power in the form of legitimated authority or power. It has often been observed that surveys under government auspices and administration have response rates well above those of private organizations. While there is a common belief that this is partly owing to the incremental effect of government authority as a prestigious and legitimate source obligating compliance or to the effect of coercive anxiety that failure to comply might jeopardize other relations with or benefits from government agencies, it is difficult to disentangle any such effects from one another and from other possible effects such as differences in the training of survey interviewers, of organizational resources, and so on. Whether Institutional Review Boards should approve all forms of legitimating auspices that may have coercive or inducement effects is problematic; even its own institution may have

legitimizing properties that affect participation.

(4) Using Particular Methods for Eliciting Information. Methods for eliciting information must be free of all elements of coercion and any undue inducement if there is to be free choice in providing information. There is considerable variation in techniques for eliciting information and the conditions for complying with the task of providing information. They must vary considerably in their coercive features; little is known about this variation from past research. One wonders, for example, whether there would be differences in responding to a typical survey question on private matters if options were routinely given to respond that it is a private matter. Again, it should be noted that we know all too little about how much falsification there is in responses to interview or test questions about private matters because respondents feel too embarrassed or constrained to say that it is "nobody's business" or that because the information is requested, they wish to withdraw their consent to continue in the survey.

There are other and perhaps more subtle ways that procedures for eliciting information coerce or constrain responses. Interviewers are trained to induce "cooperation," develop "rapport," or lead into a sensitive area of privacy. Instruments are designed to subtly lead up to the eliciting of such information; ways of indirectly measuring such responses are not uncommon. Thus one would usually not ask respondents whether they are prejudiced towards members of a particular minority or have discriminated against them in the past; more indirect methods would be used.

Inducement and subtle forms of coercion are not necessarily evident even to investigators and only a careful examination of how respondents perceive or interpret the procedure and other elements of the inquiry may

disclose them. Coercive techniques and inducements to cooperate in an inquiry, moreover, are not equally operative for all members of a study population. There is some evidence that the less educated and underclasses are more likely to be induced into consent out of ignorance or misunderstanding as to what they are free to do than are others. In general, the more the power between the investigator and the sources of information is balanced in favor of the sources of information, the less certain is any investigator to gain information on private matters. It would seem, for example, that it is easier to acquire information on theft and fraud from low than high income respondents. For that reason, a study of shoplifting may be more successfully completed with consent from respondents than let us say a study of income tax evasion. One might ponder whether many study designs should not be approved until the matter of the effect of inducements on consent is itself investigated, but that of course entails a relaxation of the strict construction.

The fraudulent use of trust is protected at law but the more common forms of deception that are practiced in social research may lie outside legal protection. While the matter of deception is explored in a separate paper for the Commission, a few additional observations are offered here since they relate to the matter of explaining procedures and measurement that must be communicated in obtaining informed consent. We shall set aside for these purposes the question of whether they cause individual harm and take those instances where the potential for harm is largely absent or minimal, particularly if there are legal protections for confidentiality and the possibility of social benefits is reasonably substantial.

It is a commonplace in behavioral science research that persons are likely to give "expected" or "socially desirable" responses to questions

rather than their "true" response. There is, moreover, a strong tendency for respondents to cloak socially undesirable responses or behavior or at least not to disclose them to persons who are not known to them. Both of these events pose problems for social measurement so that procedures are designed to measure without subject awareness of the intent of the measure. Thus there are techniques for determining whether a given respondent is falsifying responses and ways of measuring socially undesirable attitudes or conduct indirectly. Turning again to the study of prejudice and discrimination, it should be evident that both prejudice and discrimination are more likely to be measured indirectly rather than directly and certainly not directly if the identity of a subject is to be known to the inquirer.

The problem is further complicated by quasi-experiments in natural social settings, particularly public settings where the observation of behavior may be recorded. A great deal was learned in just such experiments about discrimination in employment, housing, and public accommodations or facilities. Such experiments not uncommonly are conducted using members of minority and majority groups as paid participants in the experiment and observing the responses that others make to their behavior. Through the Civil Rights Movement and subsequent legitimization in legislation, such techniques can be practiced by operating organizations as a means of gathering intelligence to enforce civil rights laws. Whether they should be precluded in research because they involve an element of deception is moot. Indeed, as we shall note later, the explicit obligation to disclose any procedures that are experimental (45 CFR 46.3:c-1) when coupled with a prohibition against deception could seriously jeopardize the status of social experiments in social problems research.

Who Must Consent?

The HEW Code of Federal regulations appears to stipulate that informed consent must only be secured for research in which "subjects are at risk." A "Subject at risk" means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service." (45 CFR 46.3:b). The operable provision for much behavioral science research is that relating to the research increasing the ordinary risks of daily life. Since behavioral scientists ordinarily deal in information processing rather than in manipulation of human subjects and social groups, the risk of disclosure of elicited information presumably increases the ordinary risks of daily life. Under that interpretation most procedures that elicit information require informed consent.

The question arises, however, whether exemption can be granted whenever a person is not exposed to risk as a consequence of "participation as a subject in any research, development, or related activity." Put another way, when is a person not a participant? This is not a simple matter in certain kinds of research. A reasonable argument may be made that systematic observation of natural social phenomena in public settings or public places should be exempted from the requirement to secure informed consent. Apart from procedural difficulties in securing that consent--a matter considered below--when persons are simply observed without any other intervention by an investigator, they are hardly participants in a research project. One might think by way of analogy to the social role of newsmen and the standards

applied as to whether consent must be obtained by a newsman to report on public events or to record them in various ways including by video-tape. One might consider also by way of illustration the research sponsored by the National Advisory Commission on Civil Disorders into the events at Kent State University. The Commission research staff utilized a large number of video-tapes, photographs, and observer accounts, including those of newsmen, to reconstruct the tragic events at Kent State. No effort was made to secure consent from the participants in those events even though many could be uniquely identified.

Frequently in social science research, a participant is a member of an organization whose behavior is examined--the object of the inquiry is the behavior of organizations or collectivities. While information might be obtained from many persons within the organization, there is reason to question whether their informed consent is required if consent has been given by organizational representatives and the information elicited pertains to their role within the organization. It is even possible that harm might result from the inquiry, e.g., that the number of positions in the organization might be reduced and some people lose their jobs; yet it is not the subject who is the participant but the organization and positions within it. The organization, for example, may in fact require assessment of job performance as a condition of employment and thereby obviate a specific requirement for informed consent. There are very special problems when an organization requires a given procedure to be followed that is both a method of organizational intelligence and assessment and an input into evaluation research. Whether employees should be permitted to decline participation in the research project if the officials authorized to consent for the organization grant consent for the research is problematic.

One might view this problem in another way. Where organizational consent is required to undertake an inquiry, their consent is essential. Whether or not that consent should be informed is unclear in some federal regulations, but clear in others. The proposed LEAA regulations, for example, require organizational consent (28 CFR 22.2). A person is defined as "any individual, partnership, corporation, association, public or private organization or governmental entity, or combination thereof" and a private person means "any person as defined . . . other than an agency, or department of Federal, State, or local government, or any component or combination thereof." Under this proposed definition all 'individuals' are 'private persons' (e.g., no distinction is made between an 'individual' acting in a 'private' as opposed to 'official' capacity) (28 CFR 22.2: Commentary). The proposed regulations require that the elements of notification be followed for all persons. They do however provide for an exception when information is to be obtained by observation or when " . . . such disclosure would have a serious detrimental effect on subject participation or purpose of research that would make conduct of the program impossible" (28 CFR 22.27:c).

There are several criteria that can be considered in determining whether the requirement to obtain informed consent may be waived or unnecessary. Each of them is briefly considered:

1. The consent of persons need not be obtained when what is observed is ordinarily open to observation by many others in the course of daily life--i.e., it is public knowledge. The exemption could extend to private places open to the public as well as to public places. As a corollary, consent need not be obtained for the observation of what is public behavior in public places. The question of whether private behavior in public places

is similarly exempt from the requirement of informed consent is more difficult to defend, e.g., making a record of an overheard conversation in a public place or during a public event with evidence of the identifying characteristics of those engaged in conversation. We shall later consider separately the matter of unique identifiers and the special conditions of consent related to them.

2. Within hierarchical organizations, the necessity to secure informed consent may be restricted to the highest level of participant representing the organization provided that the object of the inquiry is organizational behavior or aggregation across an organization or organizations rather than the persons who are members of that organization.

3. Special problems arise as to whether organizational consent is required when the object of inquiry is an organization but the information on the organization is secured solely by obtaining the informed consent of members of that organization. Should one, for example, require the consent of teachers to test the learning increment of students in their classes, or only that of the students, when teacher as well as student performance is being evaluated? There would appear to be no simple answer to that question, but it must be borne in mind that when there is substantial power to block the objectives of inquiry due solely to the power persons are given by virtue of their position, then their consent need not always be required, provided they are not coerced into participation. Put another way, information can be sought about individuals and organizations that is not strictly a personal matter, i.e., it pertains to their organizational or public roles, when their power to withhold consent blocks the objectives of an inquiry to which others grant their informed consent.

This is but a special case of a more general problem of using social

power to block the objectives of legitimate scientific inquiry when those in lesser positions of power grant their consent. Thus when a police chief refuses to grant permission for interviewing police officers in the police department regarding police work but the officers consent to being interviewed about these matters when off duty, the consent of the police chief need not be required. A refusal from persons in positions of social power to grant consent should not ordinarily preclude obtaining the same information from others who grant informed consent.

4. When consent is obtained to investigate social relationships or social settings from at least one of the participants to an event, the consent of all participants need not be obtained if that requirement would be burdensome and it is unlikely that any undue risk is occasioned by their failure to do so. There may be difficulties in determining when it is not necessary to obtain consent. Consider the following example. Suppose one wants to study the way teachers allocate time to various roles in their classroom because one is interested in how much time is spent in teaching and how much time in the role of principal disciplinarian. The observer will only sit and observe, never intervening in the process. The purpose of the study is fully communicated to the Board of Education which grants its consent. School principals are made aware that consent has been granted and are requested by the Board to participate in the study. The principals in turn inform teachers that an observer will be present in their classroom and have the Board's permission to be present and observe. Teachers in turn may introduce the observer to pupils only as someone doing research. Is it sufficient in this example that informed consent be obtained by the research investigator only from the Board of Education provided that all individual identities are protected? The problem, as one can see,

is very much tied to the question of confidentiality. Where confidentiality can be protected so that no one within the organization is privy to any information that uniquely identifies persons within the organization, only organizational consent may be required if there is legal protection against disclosure.

One reason why such a rule may be reasonable is that the procedure itself entails no risk from the procedure to those who participate as data sources in the inquiry--in brief, they are doing nothing they might not otherwise do and in fact are free to alter their behavior in the presence of an observer if they so wish. If there is any risk of harm in such situations it arises from the disclosure of information, once acquired, or from the knowledge that is applied following the research. Now if there are formal contractual agreements with organizations guaranteeing the protection of the identifying information from all, including members of the organization, and there is legal protection against compulsory and unauthorized disclosure, the need for informed consent seems altogether obviated if generalizations apply to aggregates rather than individuals.

There are difficult cases nevertheless. Consider, for example, a study of police behavior in police and citizen encounters where one has secured the consent of the police to observe their behavior. Clearly one cannot observe the behavior of the police without observing the behavior of citizens in the encounter--a common problem in studying behavior in human interactions or the interactions. A requirement that the consent of the citizen be secured before one could study the behavior of the police in the interaction is not only burdensome but might well endanger both the police and citizens under some circumstances were it necessary to secure the consent of the citizen before the police could intervene. Indeed, the

most likely result would be to foreclose that kind of research altogether since the police could hardly be expected to agree to allow an observer to observe their behavior on the condition that the observer first be allowed to secure the consent of the citizen before any police behavior could take place. This example clearly points up a complication of studying behavior in natural social settings where the intervention to secure an informed consent can itself fundamentally alter social situations and the risks attached to them! We shall have occasion to note later that the protection of confidentiality and strong sanctions for violation is critical in considering the matter of informed consent. In much behavioral social science research the only risk that exists is the risk arising from the failure of the society to grant legal protection for information. Thus in many cases the question should shift to the question of when legal protection should be given, as by a confidentiality certificate, rather than whether there should be informed consent. Informed consent is crucial when something can happen to the person because of what the procedure of inquiry does directly to the participant; it seems far less critical when the only harm that can occur arises from the disclosure of private information--a problem that is largely obviated by legal protection.

Who May Grant Consent For Intrusion Into Private Matters?

Private matters may be those of individuals or corporate bodies. Individuals generally have information about their own private matters, those of others, and those of corporate bodies. A corporate body, similarly, possesses information about the private matters of individuals and its own affairs. Clearly at issue is what may each consent to or provide information about without having secured the consent of others on whom they give

information. Correlatively, can an investigator obtain information where in securing it information often is obtained that pertains to the private affairs of others? The principle that competent individuals have the right to consent to intrusion upon their private affairs poses questions of competence and the form of inquiry. Provided that an individual is competent, consent may be given on direct inquiry. The question of age of competence to grant consent can rest in a legal age of adult status, but whether social investigators should abide by that definition of age of consent is debatable. The criteria for establishing mental or emotional competence to grant consent are far more ambiguous. Does the consent of a mental patient to direct inquiry, for example, automatically satisfy criteria for protecting subjects? Absent competence to grant consent, is the criterion of consent granted by the person or persons "responsible" for the incompetent adequate?

The question of who may grant consent is particularly troublesome when information about private affairs is secured by indirect inquiry (from others) or from the records of corporate bodies. Even where a corporate body has secured consent to disclose information for use by others, as Goldstein notes, the agreement is generally so vague or incomplete as to lack the basic elements of informed consent (Goldstein, 1969). A simple agreement that the information will be used only for research or later treatment, for example, lacks the basic elements of informed consent. The absence of specific legal prohibitions against divulging information that identifies individuals leads to much questionable use of files and dossiers of corporate bodies.

One of the more difficult questions about consent for access to information on private matters arises in securing consent on the private matters of corporate bodies since the organization often has no clear procedures for

granting consent to gain access to such information. Employees, moreover, may purport to give consent when they lack authority to do so or they make disclosures inadvertently. Without written authorization for access to specific information on corporate bodies, the legitimacy of acquiring such information is highly questionable.

An important question for Institutional Review Boards to consider is whether they can maintain a viable behavioral science while adhering to the following principles for who may grant consent:

1. Information on the private affairs of individuals shall be obtained only by informed consent on direct inquiry from the individual on his or her private affairs.
2. There shall be no indirect inquiry on the private affairs of others, or access to such information from corporate bodies when the individual can be identified by the investigators.
3. Information on the private affairs of corporate bodies that identifies the body may be obtained only on written authorization of an individual or group of that body that has authority to grant that consent.

One need not reflect long to see that such principles seem to fly in the face of social reality. Many personal or seemingly private matters arise in interactions that involve the private affairs of all parties in the interaction. Questions of the husband about the marriage relationship usually disclose private affairs of the wife. Questions asked of children about their relationships with parents frequently pry into the private affairs of their parents. In general, private matters are by definition often personal matters since they inquire into what sociologists call interpersonal relationships. The same holds true for the relationships of corporate bodies with their clients and with other bodies. Furthermore, on direct

inquiry few persons or agents of organizations separate their personal view about others from disclosing facts about others. A research procedure, indeed, can capitalize on the fact that informants do not make such separations. The willingness of persons to disclose information about others often is used to reduce the cost of collecting information. In any case, what these and many other examples can illustrate is that in the course of social inquiry, one simply cannot avoid acquiring information that could bring harm to others whose consent was not obtained. Psychiatrists are altogether familiar with this problem in treating patients; social scientists are altogether familiar with it in studying most aspects of social life. Clearly what this points to again is that the problem arises as to how to protect information from disclosure when the only alternative is to foreclose the possibility of the inquiry altogether. Considered in yet another way, to what can an individual consent without risking disclosures that depend upon the consent of others? For whole classes of problematic aspects of social life that involve the study of relationships or interrelationships and for certain kinds of techniques such as sociometric and social network analysis that are based on social exchanges or relationships, it is impossible to investigate them without acquiring information on more than a single party whose consent was obtained. There is no simple answer to that question. The suggestion that the consent of all parties be obtained before that of a single party is obtained is often unworkable since in many cases the other parties are not known in advance. Thus one cannot study friendship networks except by first discovering the friendship network. Suppose that some friendship networks include participants in a form of deviant behavior, e.g., homosexual conduct. If one began by delineating the network and followed this with queries to learn what it is that formed the basis of friendship

only to learn then that it is a form of sex relationship, one is immediately privy to information on all parties to the network. What seems required for the study of "private" social relationships and exchanges then is adequate protection for disclosure of the information secured by informed consent.

The consent process is further complicated by the question of who grants consent given the ways that persons become accessible for behavioral science investigations. The bio-medical model quite commonly assumes that the research subject becomes accessible for reasons other than the particular research inquiry. Moreover, they become accessible to investigation in settings that are controlled by persons who conduct the investigation. Typically the bio-medical model refers to clients or patients who are requesting treatment of professionals who operate in offices, clinics, or hospitals that are subject in some measure to the investigator's control. Certainly all of these settings lie beyond the control of the research subject. The fact that many subjects become accessible for research because they are at the same time in some other role relationship with the investigators, such as patient and therapist, is also critical. Even when they become accessible because they are the clients of other professionals, it is well to bear in mind that the accessibility of research subjects depends upon an institutionally organized setting and a confraternity. Where there are overlapping dependencies in role relationships such as the doctor-patient with principal investigator-subject relationships, and where the subject is in relatively unfamiliar or on alien and unfamiliar territory that lies beyond their domain and control, and where it is further complicated by an active procedural intervention on the subject, it seems essential that the research subject be able to distinguish these separate roles and what is open to choice.

There is a second model, that of subject research in total institutions, where it seems that the right of subjects to informed consent is critical. A closed institutional setting lies beyond the capacity of subjects to control. Much of their activity, moreover, is constrained and coerced by total institutional routines (Goffman, 1961:). Special attention must be given to insure that their participation is voluntary, not only by securing informed consent directly from subjects, but by insuring that the prior processes of securing institutional consent have had no effect upon subject consent. Both bio-medical and behavioral science research occurs within total institutional settings and special consent and confidentiality procedures are appropriately established for such settings.

A third model is the one already alluded to where subjects become available because they are members of organizations that make them accessible to inquiry. Here the problems exist of securing consent from multiple parties, a matter considered previously. Much of the matter of consent, as already noted, depends upon whether it is the behavior of organizations or the behavior of persons that is under investigation.

A fourth model is prototypical in social surveys and some systematic social observation surveys of natural social phenomena or occurrences. Typically, the social investigator or observer moves to the setting of the participants and must accommodate to their rules. The setting is almost entirely beyond the control of the investigator and largely subject to control by the behavior of the participants, particularly in private places. The investigator is there as a matter of privilege, if it is a private place. Moreover, typically there is no prior relationship and none is expected following the completion of the research task. Contact and communication is therefore limited exclusively to the research investigator-respondent

relationship. It would appear that the social power of those inquiring and of those of whom inquiry is made is more nearly equalized under these conditions.

There is a fifth model, where if consent is required, an abbreviated form may be all that is necessary. This is typically represented by the phone or mail survey, assuming no method of data collection that provides unique identification is employed. With the phone survey, the investigator is quite limited in both verifying information and controlling the situation. Lacking any prior role relationship, having only a short time and tenuous grounds for establishing one, and lacking most criteria for establishing identity, an abbreviated form of consent often not only is necessary if the survey is to proceed but also in keeping with the balance of social power in the subject-research relationship. There perhaps is no condition under which it is easier for a subject to refuse access, refuse to respond and withdraw from participation than by hanging up the telephone.

Generalizing across these models, one might conclude that Institutional Review Boards should pay particular attention to: (1) whether the investigator-subject relationship grows out of a prior or continuing relationship; (2) the balance of power between subject and investigator ranging from subject dependent to investigator dependent; (3) whether the research setting is subject to control by either of the parties to the inquiry or by other parties who may create an imbalance in investigator-subject power; and (4) whether the procedure of investigation alters the condition of the subject. Rules of the following sort might guide decisions. Where subject power is low relative to investigator power, there should be considerably more attention to their effects upon free choice by subjects. Correlatively, where investigator power is low relative to subject power, the requirement of

informed consent may be waived or abbreviated forms accepted.

Who May Secure Consent. Formal rules for certifying human subject research typically do not confront the question of who is qualified to secure consent. Generally the qualifications of the principal investigators are taken as the criteria for approving the solicitation of consent. A similar situation tends to prevail for Institutional Review Boards where the reputation of field staffs, survey organizations, and other specialists in eliciting information is taken as the criterion for approving the elicitation of consent. Typically the social organization of research and its growth in scale has led to the training and development of specialists in eliciting information--survey interviewers, for example, or trained social observers. While matters of pretige and reputation are guides, they are far from fallible in insuring that required procedures will be followed.

It is no simple matter to control the activities of persons whose task it is to elicit information. Generally in social research there are part-time as well as full-time white-collar employees, who have been trained in a particular eliciting procedure. Often student volunteers or assistants in training are members of the research team. When there are professional specialists, such as clinicians, procedures for certification exist; despite failings, certification provides reasonable grounds for deciding competence and trust in a fiducial capacity.

Yet it remains true that much social research is conducted by a spatially dispersed set of employees who are not subject to direct supervision and often are not under the direct control of the principal investigator. Their competence will vary considerably. This makes the fiduciary relationship between investigator and task specialist and of the latter with the subject

precarious in two ways. The subject is vulnerable to incompetence and unauthorized misuse of information as well as fraud in failing to secure informed consent. The principal investigator is vulnerable to the employee's misuse of procedure and information, thereby increasing both his legal liability and the integrity of the research process. Lacking legal protection from employee misuse of position and information and strong sanctions against violation of the fiducial relationship, it is difficult to guarantee and control confidentiality. Procedural competence can at least be partially controlled if the principal investigator either monitors or seeks ways of determining employee competence to undertake the task of eliciting information. Yet in all employing organizations there are failures, and a research organization is no more invulnerable to such failures than is any other organization. It is in fact quite remarkable that misuse of confidentiality and poor practice generally have not crossed the threshold to be regarded as problematic in behavioral science inquiry. At the same time it must be said that very little attention has been given to these matters. Where confidentiality is essential to the design of an investigation, principal investigators and Institutional Review Boards should seek information on the competence of those who elicit information.

The corporate nature of research and the size and scope of the inquiry enlarges the circle of persons who elicit information. It is essential therefore that attention be given to what forms of organizational control are exerted over employees, what sanctions are available for misuse of authority, and what procedures are followed to insure that they are properly trained in the particular eliciting procedure. Institutional Review Boards may require assurances that such training procedures are actually carried out. It is one among a number of matters that should be called for in

routine monitoring of behavioral research.

In behavioral science research procedures, generally those who elicit consent are those who terminate the research relationship. It is important that they not only be sensitive to the right of subjects to terminate the relationship at any time but that they fully inform them of any changes in conditions related to the consent. The regulations governing confidentiality certificates obligate investigators to inform subjects when a certificate is terminated (42 CFR 2a.4:8 and 2a.8). Institutional Review Boards should request assurance and evidence that subjects are advised appropriately when a confidentiality certificate is withdrawn.

Elements of Notice for Informed Consent

The Code of Federal Regulations for HEW sponsored research (45 CFR 46) sets forth a number of basic elements of information for which notice must be given in eliciting an informed consent. Each of these is considered in terms of its special implications for behavioral science inquiry.

- (1) A fair explanation of the procedures to be followed and their purposes, including identification of any procedures which are experimental. (45 CFR 46.3:c-1)

Although it seems appropriate in securing informed consent to explain the procedures that are to be followed in eliciting information from persons, it is generally correct to say that almost all of the procedures for eliciting information have little effect on persons or organizations qua procedures. Thus the procedure of interviewing that consists of asking questions and getting answers has little if any effect on persons; indeed the elements of the procedure occur in everyday life. Where the procedure has some effect on subjects because of special experimental interventions or stimuli or for other reasons, some explanation seems required. But routine eliciting procedures would appear to require little by way of explanation.

It is unclear whether more is intended by saying that the purpose of any procedure must be described other than its intended procedural use. If the purpose is to require some explanation as to the kind of information that is to be elicited or task to be performed, matters of communicating the substance of the inquiry and the goals of the investigation need to be specified. Generally in behavioral science research, any detailed explanation or description of these matters would prove burdensome and might have a substantial effect on the rate of consent. Perhaps the best rule to follow is that subjects should be advised on matters of substance if the procedure will elicit information on confidential matters, matters that are ordinarily anxiety provoking, or ones that a minority of respondents find objectionable. For many social science investigations, however, a simple statement of what procedure is to be used--a poll, a survey, an interview, watching or observing, filling out a questionnaire, completing a form--will be sufficient.

Earlier we made note of the fact that some social experiments, surveys, and evaluation studies require a cloaking of purposes or measures if they are to provide valid and reliable information. Whether persons must be advised that there are some indirect measures in the study about which feedback will be given at the close of the procedure or whether other modes of communicating must be followed is moot. Where no particular harm will befall a person as a consequence of using deceptive or indirect measures, it would seem unnecessary to require that it be communicated in securing informed consent. The full implication of this position bears scrutiny, however.

It should be clear that social scientists not infrequently seek to acquire information that persons would not provide if directly and explicitly informed of the intent by the investigator. To tell a parent that one is

interested in learning whether they are authoritarians or democrats, punitive or permissive, racist, liberal or conservative, and sexist or egalitarian in their child-rearing practices is not only unwise if one is interested in valid and reliable measures but to risk securing consent for studies that may have enormous social benefits.

What seems critical in informing persons or organizations about the procedure to be followed is that they be informed about the procedures for analyzing and reporting upon the information that is to be gathered. Generally, social scientists are interested in analyzing and reporting data for large aggregates in which it is not possible to identify individuals. It should be sufficient in many instances to simply inform the person whose consent is being sought that one is doing a statistical study where it will not be possible to identify them with any of the information that becomes public knowledge. Analyzing and reporting information for social aggregates or collectivities is an important way of preventing disclosure of uniquely identifiable information. When, for any reason, a procedure of analysis or reporting data is to be followed where it may be possible to make inferences about individual identities, persons should be apprised that is the procedure to be followed. A statement, for instance, that the information is to be presented as a case study and whether or how identity is to be cloaked in reporting is a minimum of what must be communicated in such instances.

There are types of social research where it is especially difficult to describe the procedures to be followed or where their full disclosure imposes limits on the technique. Three of these are singled out for special attention: exploratory studies, participant observation, and systematic social observation.

Exploratory Research. It is particularly difficult to satisfy the

criterion of informing about procedures and goals of inquiry in research that is essentially exploratory in nature and where no specific procedure is to be followed, a situation that is not uncommon in behavioral science research. This is often the case in solo-field or participant-observer research and in case studies. The investigator may utilize a host of exploratory procedures including observation and interviews, group discussions, life history techniques, personal documents or records, participation in events, and even assuming social participant roles in everyday life. Questions in exploratory surveys more often seek an open-ended rather than a closed or fixed response. The use of probes in exploring the information that will enlighten, inform, or explain do not lend themselves to predictable types of information that will be acquired. Such techniques may quite often obtain considerable material that is extraneous to the problems under exploration and may be matters which the subject would not otherwise disclose. Yet the acquisition of new knowledge must permit reasonable exploration. While a simple statement that the investigator wants to explore certain topics or matters will not suffice to inform the subjects of participants from whom information is sought, their permission to, quite frankly, "explore" or "look at in-depth" a number of matters should be allowed if an Institutional Review Board and Peer Review Committees consider the problem significant, if alternative ways of investigating the matter are not as promising, and if the investigator can be trusted to fulfill at least those conditions of notice which are applicable (such as allowing persons to refuse answers or withdraw from participation).

Participant Observation poses special problems of satisfying the criterion of "informed consent" since the observer utilizes ordinary social roles as well as that of investigator to acquire information or to legitimate the

observer role. Apart from questions of deception that arise when the dual nature of participation and observation is not explicitly stated, participation itself may be utilized to gain an advantage before any information is gathered. Thus participation may serve to develop a trust relationship which then might be exploited by seeking their consent to serve in a research role. The participant observer role, as previously noted, poses special problems of consent generated by the intersection of several different roles in the same person. There seems to be more rather than less need to inform about the research role in participant-observer as compared with observer studies since the role of observer is easily confused with the role of participant.

Systematic Social Observation is constrained, as previously noted, by difficulties in determining whose consent is required. There are, however, important limitations on securing consent from individuals who are being observed, limitations imposed by practical considerations of implementation, timing, and unpredictability about precisely who is to be observed in particular settings. It might not only be impractical to secure the consent of all persons at a public meeting but certainly it would be difficult to single out in advance all persons who might be active participants on which the observation would concentrate. At times one can follow the procedure of announcing that one is present as an observer or one can secure the consent of persons in authority in the setting, but where these are not feasible there are few substitutes for securing the consent of those under observation. The extent to which one will forego the requirement of informed consent in systematic observation always will depend, of course, on an assessment of the risks involved in observation and protection afforded against harm from disclosure.

- (2) a disclosure of any appropriate alternative procedures that might be advantageous for the subject. (45 CFR 46.3:c-4)

This requirement of notice derives from a bio-medical model of research where the role of investigator intersects with those of other roles such as that of medical specialist who has diagnostic or treatment options to that of the research procedure. Alternatives also exist when there is more than one form of diagnosis or treatment, etc. When the role of experimenter is merged with that of impartial investigator, alternative forms of experimental procedures may be possible. Alternative procedures may also exist in studies that involve social intervention and evaluation of it or in participant observation. In such cases there is likewise a merger or intersection of other roles with that of investigator.

Most of the time, however, the question of advising about alternative procedures that might be advantageous to the subject is inapplicable in behavioral science research because the nature of any anticipated benefits does not involve a calculus of alternative procedures. Ordinarily, behavioral science inquiry does not promise benefits to research participants as a consequence of participation. Thus it is not germane to define alternative procedures that might be advantageous to subjects. Indeed, there are strong prohibitions against using procedures that may be more advantageous to subjects in behavioral science research on the grounds that such advantages may bias the results of the inquiry. That of course is an empirical question.

- (3) an offer to answer any inquiries concerning the procedures.
(45 CFR 46.2:c-5)

Quite obviously, any person in direct contact with a research subject or participant should answer questions about any of the elements that are stipulated as the elements in notice. There are certain other kinds of information, nevertheless, that a social investigator often supplies by

way of notice and about which there must be direct answer if direct inquiry is made. These include the following:

1. The person who seeks to elicit information or make any other procedure operative must provide a unique identification of self on direct inquiry. Ordinarily this should be done as a part of the procedure in securing informed consent. A subject has a right to know to whom information is given or who is performing research procedures; this might well be an element of notice in informed consent. The complaint form and the warrant or testimonial discussed later will provide documentation of persons who secure informed consent and undertake any procedures directly on a person.

2. Requested information on auspices and sources of financial support should be answered on direct inquiry. Where promise is made to provide that information in the event that a particular employee is not familiar with the information requested, evidence must be provided that it was made and supplied. Normally, however, every employee who interacts with subjects should have a reasonable amount of information on auspices and sponsorship and principal investigators should be held responsible for informing them.

3. Any request for information about unique identifiers whether by means of data collection or other modes of identification should be supplied. Questions about modes of observation and recording and whether they carry unique identifiers must be answered by an employee when questions are asked.

4. Any request for information about mechanical aids to information recording should be answered, including information about how that or any other kind of information is to be protected, for how long, etc.

We have had occasion to note that when procedures cloak some of the objectives of the inquiry, investigators may be excused from making those explicit if the result is to seriously damage the validity and reliability

of information and no particular harm attends most subjects who are involved in the procedure. Despite this exemption from affirmative action, it appears reasonable to stipulate that should any person explicitly inquire whether there is deception in any form, one must not only offer to answer, but to answer truthfully, so as not to deceive on direct inquiry.

In brief, remembering that employees are members of an organization, all employees who have roles for eliciting informed consent or performing any research procedures directly on persons should be given sufficient information so that they may answer directly the questions stipulated above and any others deemed essential to informed consent.

- (4) an instruction that the person is free to withdraw consent and to discontinue participation in the project or activity at any time without prejudice to the subject. (45 CFR 46.3: c-6).

The promise that the subject is free to withdraw consent and to discontinue participation at any time poses special problems for both subjects and investigators. One question that can be raised is under what conditions is that promise compromised by the consent procedure or the methods of inquiry undertaken by the investigator.

First, whenever inducements have been offered to subjects to reward them for their participation and they are so advised at the time to consent, the inducements, particularly money, may affect any person's willingness to withdraw. It should be apparent that investigators should not offer inducements that are contingent upon completion of a particular task unless it is a matter of formal contract. Otherwise they can easily compromise a subject's wish to withdraw.

Second, any promise of withdrawal is operative only at the level at which it is communicated. When consent is obtained for organizational

personnel to participate in an investigation, there should be explicit agreement about whether such persons may voluntarily refuse to provide information or withdraw from participation. When it is agreed they may do so, it should be explicitly communicated to each participant. To illustrate, if a police command agrees that an observer may ride with the police in his command to observe their behavior and that they have no right to refuse to cooperate with the observer, it is his rather than the observer's obligation to communicate that to officers and the observer has no right or obligation to advise the officer that he has a right to refuse or withdraw.

Third, a promise of a right to withdraw or refuse to participate in cooperating with some aspects of the procedure may lack force where there are strong pressures from other sources to continue participation as noted in the discussion of inducements. Care should be taken to minimize the force of such pressures when they cannot be eliminated altogether by virtue of the fact they are natural social phenomena.

Fourth, the promise of refusal or withdrawing may be an inadequate protection with some procedures and neither the person who elicits information or controls participation nor the person who is advised of the right to withdraw may be aware of the subtle ways that the decision to refuse or withdraw is brought to a threshold of consciousness and therefore raises the matter to a decision level of refusal or withdrawal. Where behavior or responses to stimuli, including verbal stimuli, are sequenced, much information may have been given that the subject may wish had not been given after the threshold is reached. This is not an uncommon result when interrogation is followed in intelligence gathering procedures; it may also occur in research techniques of questioning. A question arises whether persons who

consent to participate should have such control over the information provided that they may demand that information already given now be withdrawn. Thus subject refusal or withdrawing may be inadequate when the person wishes to withdraw matters that are already a matter of record.

Even were one to grant some right to expunge the record, there are real limits on the capacity to do so. One can expunge a written record, return a questionnaire or test that was completed, or in other ways destroy matters of record, including the record that consent was given! Whether such an option should apply to a right to expunge the record of consent is problematic. Yet, there clearly are conditions under which a person might wish to make that request such as when that record of consent or refusal to consent is incriminating or damaging to the participant. Limits to expungement arise, moreover, from the fact that one cannot obliterate the memory or experience of others. The most that could be required in such instances is an explicit prohibition against the use of such materials in any form or for any purpose. That is not, however, an enforceable rule where memory is at stake absent explicit evidence of use.

- (5) Any institution promising to place any subject at risk is obligated to obtain and document legally effective informed consent. No such informed consent, oral or written, obtained under an assurance provided pursuant to this part shall include any exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights, including any release of the institution or its agents from liability or negligence.

One assumes that statements made to subjects holding that any assistance given to the subject cannot be regarded as an acknowledgement of liability or negligence by the institution or any of its agents are not exculpatory since they do not represent a disclaimer of responsibility for conduct but pertain to evidentiary questions at law.

It is unfortunate that the traditions of tort liability in American law place such heavy emphasis on fault and negligence and fail to lay stress upon affirmative duties or responsibilities. Where human subject research exposes subjects to risk and there is reason to believe harm has occurred, tort doctrines might better stress affirmative responsibilities--the moral and legal obligation to give help. There are some exceptions in American law of affirmative doctrines, such as the Good Samaritan laws to protect heroic and other civic actions from tort liability. In human subject research, special consideration might be given to developing some exemptions from tort liability where the desirability of affirmative actions outweighs protection provided by tort liability.

- (6) a description of any attendant discomforts and risks reasonably to be expected. (45 CFR 46.3:c-2)

From the perspective of behavioral science, this requirement of notice is unduly restricted by the bio-medical model of Human Subject research unless one construes the reference of "attendant discomforts and risks" to include any discomforts or risks that follow both directly and indirectly from participation in the research. It bears reminder that in behavioral science inquiry major risk of harm attends primarily from the disclosure of private matters rather than from specific procedures for eliciting information or the performance of tasks during the eliciting procedures. We shall assume that in behavioral science research the broader construction applies and merits close attention from Institutional Review Boards.

Considerable difficulty attends the operationalization or interpretation of the constraint "reasonably to be expected." Is that criterion to be applied on the basis of expectations for a population of all possible subjects? For a particular subject whose consent is being secured? Or, for the population at risk in the given research study--a population whose dimensions

are only generally known, e.g., a random sample of the U.S. population? Is one obligated to assess separately risks for subclasses of a population--those identified by race, age and sex, for example? Or does one choose to adopt the risk in using a given procedure--survey research, for example?

To have an exact probability for a population "at risk" is unlikely not only because it is difficult to obtain such probabilities but also because such information is at most available for some related population and one would have to assume that risk applied. Moreover, knowing the probability does not provide a decision rule for an investigator or an Institutional Review Board. Even a rule that the benefits must exceed the risks is unsatisfactory in itself, not only because as already noted such ratios cannot be applied to all behavioral science research but because both the level of the risk and the ratio of risks to benefits are at issue. There is a strong likelihood, in fact, that different Institutional Review Boards will adopt different decision rules both for a given level of risk and for cost/benefit ratio, thereby leading to inequities among investigators. The problem, of course, is not unique to scientific research since it is characteristic of all discretionary decision-making in systems where equity is at stake.

There are also no clear guidelines in the regulations for the choice of a base to assess risk. Social scientists would ordinarily think in terms of probabilities of harm for a given population that is "at risk" or of an actuarial base. Yet if choice of risk and base population are permitted, one might opt for the risk element and the base that give the lowest risk. To illustrate, there is a fairly low probability that the survey method ever leads to employee disclosure of confidential material; enough evidence is available to permit one to conclude that the use of the survey method cannot

reasonably be expected to produce unauthorized disclosure. Based on the risk of using the survey method in all studies, one would conclude that in the ordinary use of the survey, informed consent is not required. Similarly the risk of compulsory disclosure from the use of subpoenas is so low for all studies or even "sensitive ones" as to "obviate" the need of informed consent. If, however, the relevant criteria are the population at risk to a particular study where the population already is at risk for harm from past behavior, e.g., a population which is asked to report violations of law during the past year, the problem is not easily resolved as to whether their informed consent is required. On the one hand one might conclude that the risk of disclosure has been very low in such studies, but on the other hand the potential harm is not inconsiderable in a given case.

There is, of course, the additional matter that a guarantee of confidentiality may be necessary to secure consent from the members of a population that perceives its risk to be high, e.g., criminal offenders or drug users. The relevant criterion here shifts to subject perceptions of risk of harm rather than to an actual assessment of risk from harm. Where confidentiality is at stake, one perhaps must recognize that no simple rule of whether or not informed consent is mandatory is easily formulated. But, in any case, adequate legal protection has the capacity to reduce many social risks. It can be maintained, nevertheless, that in exchange for legal protection one is compelled to follow rules of informed consent, a requirement that proposed regulations follow (43 CFR 2a.4 and 28 CFR 22.26).

The problem of risk assessment is, in any case, closely linked with the necessity to guarantee the unique identity of persons and information from disclosure if subject cooperation is to be secured. Where the procedure

guarantees anonymity in the form of data collection as in the anonymous completion of questionnaires, the risk is close to zero. Yet the anonymity procedure cannot be instituted without consent to participate, though the extent to which consent must be informed to secure anonymous participation is moot.

With some exceptions, to be discussed later, behavioral science research when gathering information that has unique identifiers has no interest in reporting information with unique identifiers. This follows from the fact that most behavioral scientists have an interest in aggregative levels of information. It is most easy to disaggregate data gathered from persons, families, and households, and most difficult to report it for certain kinds of corporate units such as multinational corporations. Much depends, however, on the number of units in a defined statistical universe and whether or not that universe is identified. Thus one could do some disaggregation in reporting analyses for 200 teachers but if they are all identified as coming from the same school, the level of disaggregation possible before unique identification occurs is much less than if the 200 teachers came from all schools in the United States. It would be relatively easy, moreover, to identify the male physical education teachers in a single school but more difficult if the sample were from 200 schools. Yet some possibility would exist even at that level of disaggregation for the 200 national schools. Disaggregation must follow rules of its own to prevent disclosure.

There are situations, however, where reasonable expectations are that considerable risk may attend the securing of information because one is unable to protect the data against disclosure should one be compelled to do so. That condition arises whenever the State, at law or otherwise,

compels disclosure. At law within the United States, absent statutory protection on disclosure, one may be compelled to disclose in response to subpoena, for example. The risk of coerced disclosure is considerably greater in comparative national research, however, since the capacity of foreign nationals to protect their data is generally without legal guarantee. The risk may be considerable in some societies for kinds of data that ordinarily pose little or no risk in American society. Whenever research is to be undertaken in foreign countries, Institutional Review Boards must give close attention to the capacity of investigators to protect their information even when informed consent is elicited, lest one become an agent of harm.

The necessity of notice, however, hinges in part upon the definition of "subject at risk" already discussed. The HEW requirements in the Code of Federal Regulations stipulate that a subject is at risk when he " . . . may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activities which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service" (46 CFR 46.3-b). It is hard to say that most behavioral science research in any way is necessary to meet the needs of most subjects or that there is no possibility research does not increase the ordinary risks of daily life or those inherent in an occupation or career. Possibilities always exist. I suppose that the possibility of psychological harm always exists and an operable question is whether a social research procedure has any more risk of psychological or social harm than the ordinary risks of social life. Think for a moment

whether most behavioral science studies of pupils in schools are any more likely to do psychological or social harm than that done each day to pupils in many schools. My impression is that research suggests many teachers do more harm to students than do most investigators. Should one conclude then that because research in schools ordinarily does no more harm than that done every day by their teachers, one is justified in approving a proposal? What criteria are to be applied? Or consider another example: may the police ordinarily not do more harm to citizens than observers of police and citizen transactions?

These examples are not offered to suggest that the risks of social science research do no more harm than the risks of everyday life or, if indeed that were true, that one should conclude that the criterion creates a tolerable level of risk in the society. They are intended rather to show that we know very little about the nature of risks in everyday life and that to know more is in itself an empirical question that would involve research on human persons and their organizations. There is danger that Institutional Review Boards will "create" risks that have little if any empirical foundation. The substitution of "informed guesses" is hardly a satisfactory solution to the problem, particularly in the assessment of risk. There is ordinarily a considerable range to subjective probabilities for any phenomenon. An Institutional Review Board is hardly a large enough sample to create even reliable estimates of subjective probabilities. In any case the relationship between subjective and objective probabilities can be positive or negative and they are often far from perfectly correlated.

The Concept of Social Harm. It likewise is far from clear what is intended in defining the concept of "social harm" since it is not defined beyond the conception of "subject at risk." There is some implication that again what is intended flows from the elementary Human Subject model.

Social harm in the restricted sense would refer to the social consequences for a subject. Such harm might range from a temporary experience of anxiety or forms of social embarrassment to far more serious consequences if private matters become public knowledge or are disclosed to persons who may wield social power over individuals. This can include the imposition of penal sanctions, loss of employment, social isolation or ostracism, and divorce, to mention but a few possible consequences that befall some persons when some private matters are privy to others. We have repeatedly noted that social harm in behavioral science research most usually would come about as a consequence of these latter sources of social harm, i.e., private matters become privy to others who then do harm. Investigators and their methods are not ordinarily a source of serious harm to individuals apart from harm through disclosure.

There is another type of social harm, however--that which may befall corporate actors or collectivities when their behavior becomes public knowledge. A few illustrations may suffice to make the point. Disclosure of the financial condition of financial institutions might lead to a "run-on-the-bank"; disclosure of an impending stock transaction within an organization might lead to the illegal act of "insider trading" (it is assumed the principal investigators would not become "inside-traders"!). The disclosure that a particular employer discriminates against minority employees in employment could lead to legal actions against the firm. These are all instances where the disclosure of information that an investigator may acquire may do harm to corporate actors. If that information was acquired with a promise of trust, as is often the case, the investigator becomes an agent of social harm in this broader sense.

It is inevitable, however, that some forms of social research do harm

when results are published--literally made public. Investigators cannot promise that their inquiry will reach a predetermined conclusion and indeed, given the nature of their fiduciary responsibility as scientists, they cannot offer such promises. Results do not usually intend harm, but they may bring harm to corporate actors and their individual members. Where evaluation research is undertaken, as already noted, both social harm in the restricted sense of harm to persons and harm to corporate actors may occur with the disclosure of the results from a given inquiry. Evaluation research often requires at least limited disclosure of identifying characteristics for the corporate actor.

An important and major ethical dilemma is created for behavioral scientists when they enter a research relationship and extend a promise of a guarantee, including a legal guarantee, of confidentiality. Any promise of confidence prior to the disclosure of what must be held in confidence can become a source of a moral dilemma. Disclosures in confidence that acknowledge grievous social harm raise the question of whether an investigator is obligated to disclose the harm despite the promise of confidentiality. This dilemma is commonly faced by professionals in confessional or counseling roles. In general the norms that apply to such roles would appear to apply as well to the investigator's promise of confidence. Yet it seems unethical to extend such a promise if there are circumstances under which one cannot reasonably control unauthorized disclosure, as when legal protection against compulsory disclosure is absent. For many types of private matters, approval perhaps should not be given when disclosure would bring substantial social harm--benefits aside--and the investigator has no formal legal sanctions or protection against disclosure.

One other matter about social harm should be clarified. It is appropriate

for Institutional Review Boards to weigh the matter of harm both absolutely and relatively. Harm is weighed absolutely when there is no reference to its relationship to potential benefits. Certain kinds of research and certain research procedures may be ruled out on moral or legal grounds, e.g., wire-tapping or electronic eavesdropping, with no reference to potential benefits. Most of the time, a calculus of cost-benefit is applied to determine whether a project may be approved. Generally if potential benefits outweigh social harm or costs, there are reasonable grounds for granting approval by this criterion of notice.

Yet there are types of behavioral science research where a harm/benefits ratio is inappropriate. The harm/benefit ratio is often inappropriate in the study of corporate actors, as a consideration of examples may make apparent. First, since in much evaluation research or in quasi-social experiments the outcome is not predictable, neither the social harm nor the social benefits to corporate actors can be calculated in advance of the actual investigation. Moreover, as already noted, an investigator cannot promise benefits from the results of the inquiry, though if some form of compensation is given by way of inducement, in a trivial sense, that might be thought of as a benefit. Second, in yet other cases, what is social harm may be simultaneously social benefit. A conclusion that a substantial proportion of banks have high risk investments can bring harm to these banks by bringing on an investigation of all banks during the course of which their condition is discovered and sanctions applied. At the same time, the disclosure may lead to increased control of the banking industry in the public interest--a rather clear social benefit. It should be apparent that this instance is rather different from the oft cited bio-medical example where one must first do harm to cause wellness, or to say that the first action

is not harm since its intent is wellness. Social scientists may well have similar examples but in the type case just presented, the same information causes both corporate harm and corporate benefits, albeit it to different corporate actors. It follows, of course, that it can be simultaneous for the same corporate actor and its members.

Mention already has been made of the need to protect persons and corporate bodies from the disclosure of private matters whether or not there have been promises of confidentiality. There is both a legal obligation to maintain such confidence when there is a prior fiduciary relationship and a moral obligation to do so when intruding upon the privacy of others.

The matter of protecting the integrity of corporate bodies is one that is particularly troublesome for behavioral scientists. On the whole, less attention is given to preserving the anonymity of private matters of corporate bodies, yet the basis for doing so is not altogether clear. There is little evidence that the socially harmful consequences of such disclosure are examined, though in some kinds of research the investigator may actually "intend" harm, as research undertaken in the spirit of muckraking sociology or social criticism (Marx, 1973). Social harm may flow also from the design of much evaluation or action research where the disclosure of identity is built into the study design.

Risks of damage or harm exist as well for corporate bodies that are the sponsors of behavioral science investigation. There is ample evidence of the political risks occasioned by scientific research (Shils, 1956) and behavioral science investigation (Sjoberg, 1967). Behavioral scientists and their sponsors also assume political risks in competing with journalists (Horowitz and Rainwater, 1970), lawyers, and other organized modes of inquiry

as they challenge more traditional and established modes of inquiry with claims of "scientific truth."³ Congressional investigations of private foundation funding and of grants from public agencies for research into controversial social issues and their ethical standards in research on human subjects impose political risks and governmental control over inquiry. On the whole, behavioral scientists have been given to view these investigations as attacks or threats to academic freedom and free inquiry. They are less commonly viewed as risks and moral dilemmas for such organizations, which they often are as well. The moral dilemma of university sponsors such as that of Harvard University faced with a broad mandate to protect students, academic freedom, and the reputation of the university in the psilocybin research of Leary and Alpert (Benson and Smith, 1967) is given much less attention. Yet in that case, as in many others, research sponsors are moved to institute controls over investigation as a resolution to political and moral dilemmas. The moral imperatives of protection with their attendant risks become a central focus of any organized effort to control bio-medical and behavioral science inquiry.

The question of how much social harm may result from a particular inquiry is often closely linked to whether or not an investigator may forestall potential harm or take steps to protect from social harm. We shall examine below some of the matters that raise problems of protection, particularly those related to unique identifiers and the public disclosure of matters that cause harmful reactions. At the same time we shall briefly consider the matter of protection from harm, though that is treated more extensively in the third section on confidentiality.

Unique Identifiers. A unique identifier is any information that will

permit someone other than the actor to whom the identification applies to identify that actor, whether person, corporate, or collective. When any other information can be attached to a unique identifier by ordinary evidence, a disclosure problem exists.

Unique identifiers will vary in terms of the evidence they provide for exact identification according to rules of evidence and inference. Some identifiers have a high degree of precision, e.g., fingerprints or voice-prints. Photographs are somewhat less precise means as are signatures but their evidentiary value is substantial. Other identifiers are still less exact such as names and addresses. Still others require more inference from the evidence such as the race, age, and sex of a person at a given address. It follows that the more exact or unique the identifier by evidentiary rules and the less inference that is necessary in making a unique identification, the more protection that should be provided if harm may result from disclosure.

The unique identification problem in research must also be viewed in terms of potential processes of disclosure: how the unique identification is made to bring about the disclosure. We shall not review all such ways but note that all ways relate to how access to unique identification and other information is obtained and how one becomes accessible to physical and testimonial evidence. Both present substantial problems for behavioral science research.

Access to Physical Evidence. Clearly access to exact identifiers such as voice-recordings, video-tapes, photographs, and fingerprints pose very special problems for social research. Such unique identifiers pose special questions of whether they are necessary to the inquiry, what protection is provided to access, and how long and how such records are retained. Not only

should considerable precaution and security attend their acquisition and retention if they contain potentially harmful information, but some provision must be made concerning their retention and eventual destruction as forms of evidence. Destruction should be guaranteed where applicable and under some circumstances Institutional Review Boards should require stipulation of these plans. Destruction of exact identifiers should wholly be provided for at the conclusion of research, except under the most extraordinary and compelling circumstances for their retention in subsequent research. The earlier destruction can be feasibly undertaken, the more security provided.

It should be apparent to all involved in research that absent legal protection for unique identifiers and the other information related to them, they constitute damaging forms of evidence when there is potentially harmful information. It should also be apparent that it is far more difficult to erradicate testimonial than physical evidence. These are compelling considerations where serious damage may result from disclosure of information with unique identification.

Access to Settings. When physical or oral evidence is obtained, it must occur in social settings. Social settings vary considerably in their access to other than authorized research persons. The same holds for access to processing and storage, once information is acquired. Private places are less accessible to both authorized and unauthorized intrusion, for example, than are public places. Vulnerability, therefore, is greater in systematic social observation in natural social settings than in contrived ones in private places. Where potentially damaging information is obtained, there must be reasonable means of protection against access during the data acquisition, processing, and storage phases. Above all, Institutional

Review Boards should be mindful of the fact that access during acquisition is often the most vulnerable of social settings in the research process, at least from an evidentiary perspective. We would remind again that foreign settings are generally more vulnerable than domestic ones, that public places more so than private places, that natural more so than contrived settings, and that physically unprotected more than protected settings. Where the possibility of testimonial evidence exists--as it usually does unless the procedure is constructed so as to provide anonymity from all persons involved in the research process--the problem deserves special attention.

Note should be taken here of a separate but related issue, that of dangers to disclosure by the access given through didactic use and in dissemination through agents other than those of scholarly publication. An Institutional Review Board may wish to grant approval subject to some constraints on either mode of access. Didactic use of confidential information is common in teaching and training of research specialists and practitioners or in other forms of training. Where serious harm could result from disclosure of information, it is doubtful that unique identification should ever be allowed in behavioral science teaching and training. The problem is a more difficult and serious one in bio-medical research where living subjects are used in training. The problem is a critical one since protection is generally afforded only to employees. Students, trainees, and others who are not employees ordinarily are not qualified for protection unless specifically appointed as employees.

Similarly, the sharing of confidential information where unique identification is possible with colleagues and its dissemination through forums and media must be carefully protected. Sharing such information

with journalists is particularly risky and its sharing for any public purpose such as law enforcement or regulation must be precluded and legally protected.

Testimonial Evidence. Little need be added to the problem of testimonial evidence than has already been said. Given the special vulnerability of testimonial evidence, viz., that it cannot be totally eradicated except under the most extreme of measures taken against persons (and means that must be morally repulsive to any scientific investigator, e.g., homicide), it presents special problems.

The first problem is that of unauthorized disclosure and deliberate misuse by members of the research team or others who obtain unauthorized access. While there are some legal protections available in both tort and criminal law to sanction persons who deliberately misuse or disclose damaging confidential information, they are ordinarily weak remedies for those harmed and they do not provide any means of preventive control for those responsible for their protection in the research process. It is unlikely that reasonably effective preventive control can be provided institutional sponsors and principal investigators unless there are strong and specific legal sanctions against unauthorized disclosure and misuse that is inadequately protected by tort and criminal law. Such protection is provided for in the LEAA proposed Code of Federal Regulations (28 CFR 22.29 and Commentary).

The second problem is that of compulsory disclosure through trial proceedings and subpoena. Behavioral science research has proved to be increasingly vulnerable to the threat of subpoena (Nejelski and Peyser, 1975: B12-B24; Nejelski and Lerman, 1971). Adequate protection in this respect would seem to be provided in the HEW proposed Code of Federal Regulations

that stipulates: "Persons so authorized may not at any time be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify the research subjects encompassed by the Certificate except in those circumstances specified in paragraph b of this section." We shall have occasion to refer to those exceptions later. I make special note of the caveat "would seem" since these are complicated legal matters and the Code of Federal Regulations is itself subject to subordination by present and future Federal legislation on specific matters and the constraints of the Privacy and Freedom of Information acts. There is and will be case law and there are related constitutional issues.

Just how much of the information on risks should be communicated in securing informed consent is problematic. A requirement of full disclosure to secure consent could be burdensome and have consequences for the reliability and validity of information. It follows that the more one is legally protected and the more sanctions that are available to forestall disclosure, the less specific information need be communicated. A simple statement that states the form of protection that is available may often suffice, particularly when there is strong protection as with legal protections for confidentiality and disclosure.

Potentially Chilling Effects of Full Information. Behavioral science investigators may well overestimate the possibilities of the chilling effects that full disclosure of the information required by the elements of notice may have upon cooperation and the reliability and validity of information. The problem is not a single one since compliance with a full disclosure rule may not only create a greater possibility for free choice but also raise unrealistic doubts and concerns that are damaging to free inquiry.

We do not propose to discuss the problem fully here. We would simply

note that some matters would seem more important than others such as the necessity to inform about unique and exact identifiers and what protections are afforded for confidentiality.

There is, nonetheless, one special problem that deserves attention. It is axiomatic that any form of regulation has possibilities for its evasion and that any form of protection has possibilities for leaving one vulnerable to harm. Both require brief comments. First, patterned evasion will inevitably develop among Institutional Review Boards and among Principal Investigators if requirements unduly constrain free inquiry or prove unusually burdensome. Second, current regulations now provide a possibility for leaving persons vulnerable and unprotected on evidentiary grounds. A single example may call attention to this. The requirement of a written and informed consent signed by subjects provides signature evidence and ordinarily provides fingerprint evidence as well. Were such evidence to be either secured by compulsion or otherwise, and since such evidence can be damaging to persons, that particular requirement has made for greater possibility and perhaps likelihood of harm!

We note one other related matter in passing since we shall have recourse to consider it later. The bureaucratization of regulation may easily prove burdensome and lead to patterned evasion as well. A requirement, for example, that one keep a log of all persons who have had access to confidential records may readily lead to evasive tactics and more rule-making which in turn may generate evasion.

- (7) a description of any benefits reasonably to be expected; (45 CFR 46.2:c-5)

The elementary Human Subjects model is predicated on the presumption that ordinarily participants in research are subject to some other form of

intervention that is designed to benefit the participant directly. The research intervention is coupled with another form of intervention that is designed to do good. That model is largely inapplicable to most behavioral science research even when good may result from the research. This is so for a number of reasons.

First, and it hardly bears repeating, most participants in social science research are related to investigators solely through the research role; there are few if any direct side benefits.

Second, most behavioral science research has an interest in descriptions for aggregates rather than individual or corporate units and seeks generalizations at an aggregative level. Disaggregation to the point of unique identification is rarely useful for the dissemination of knowledge.

Third, where benefits are possible, they ordinarily arise from the production of knowledge that will help an aggregate or class, of which the participants are only representatives. They are thus class rather than individual benefits. Benefits, moreover, often may not flow from a particular inquiry, except to the scientific community, since a particular benefit may flow only from the cumulation of knowledge.

Fourth, in many cases, the benefits, therefore, are not predictable in advance and we would remind again that the same knowledge may bring both harm and benefit.

Fifth, the benefits from behavioral science research often are expected to redound to the sponsors of research. Most assuredly many federal dollars are spent on behavioral science research not only because the government is operating in its general role of public interest and welfare but in its more special one of making policy and program decisions. Evaluation research and program research is expected to bring pay-offs in practice and in decision-making.

Put another way, the beneficiaries of behavioral science knowledge are generally principals and third parties. Investigators may be rewarded for discovery and additions to knowledge. The public interest may be served collectively. The sponsors may make practical use of the knowledge.

Much behavioral science research has engineering, enlightenment and intelligence benefits only (Crawford and Biderman, 197). The most usual benefit is enlightenment for a scientific community and the public. It becomes an element on the basis of which they can more intelligently relate to the problems before them, either as citizens, officials, or workers in some other role. Behavioral science knowledge has a special relationship to the making of social policies and serves therefore an intelligence benefit. The policy-maker utilizes the special knowledge to sense the problem and actions that may be taken. But it is only one of a number of elements in the formulation of public or private policy. A third use is its engineering benefit, its utility in direct use of application. As an example, a study of the use of a modus operandi file in police work may result in immediate changes in the structure and use of that file.

There is, naturally, as in all science, a reasonable amount of what is called basic science research, the acquisition of knowledge that will make new knowledge or increase the production of knowledge. To forecast the benefits of a particular study to basic science is precarious at best.

FOOTNOTES

1. There are some statutory limitations on consent where proprietary interests prevail or when exchanges are privileged.
2. The more unplanned the intrusion into private matters, the more complicated are problems of "informed consent" and "protection of the sources of information," matters treated below.
3. Note that I do not argue that we have a more legitimate claim to "truth," whether or not it is made in the name of scientific inquiry, but simply that our claim to science opens us to political challenge.

These matters considered, cost-benefit decision rules in decisions to grant or withhold approval are both troublesome and inapplicable. A few additional issues are raised however with reference to the element of benefits in notice and these are now considered.

Participation in behavioral science research often may involve benefits that are particularly difficult of measurement, viz., psychic benefits. Studies of the old and retired, for example, often report the pathos of the pleasure that their attention brought to those who are all too often socially isolated and neglected. The psychic benefits of prestige, satisfaction, and a sense of achievement are open to exploitation in research but more often than not participants regard them as benefits. I do not know how they can enter in any precise way a cost-benefit calculus. Even were research to provide us evidence for inference and prediction, that research ordinarily is not available and not obtainable without prior research on persons.

Protection Against Disclosure. There is no explicit provision in the elements of notice to stipulate that participants be informed of the nature of the protection offered against disclosure. Presumably that matter is included among the risks one might stipulate. There is reason to maintain that it should be an explicit element of notice in securing informed consent. The obvious reason is that it is potentially very harmful. But there are other reasons. At least where confidentiality is at issue, as it is in any research where unique identification is an element in the design, there is a problem of special protection. All persons and corporate bodies have a right to know to what extent they are protected against disclosure whether or not the investigator defines the information sought as a private matter; subjects may regard it so. If they

do, there is even a potential side-benefit for investigators if protection is afforded: it may increase the participation rate and enhance the validity and reliability of the information. Moreover, many studies must make representations about confidentiality. Institutional Review Boards ought to know what those representations will be. It seems intolerable to permit the extension of confidentiality when protection is weak or unafforded. Both Boards and participants should be informed of protection against disclosure.

The Extent to Which Notice is Explicit and Full. Apart from the problem of potential chilling effects already alluded to, questions arise as to how one will decide how explicit and how full notice shall be. What rules shall guide decisions about the form of notice. A criterion of reasonableness, for example, must be guided.

The problem of information overload is a common one in information processing and research participants are also subject to information overload. Overload may not only constrain free choice because it makes matters "too clear" or unintelligible but it may also induce compliance to unduly impressing some potential participants. When people do not understand, they do not always withdraw; they may want to find out more or believe that it is a good thing to go along with something which is that impressive. It is well established that given differences in levels of education and comprehension, a single form of notice must be intelligible to those with the minimum education and comprehension for the population under study.

Forms of Documenting Informed Consent

The elicitation of informed consent is primarily a matter of procedure

or method. Our previous discussion focused on the requirement that regardless of specific modes of elicitation and procedure, they must permit "free choice." To some it may be surprising that both recommended and approved federal regulations for informed consent do not similarly permit the participant to chose whether or not the agreement to participate is documented by the participant in some form of unique identification. The decision that the participant or his/her representative if they choose to consent must give written consent, unless the investigator is exempted from the requirement to obtain informed consent, is a restriction on the participant as well as the investigator and is a constraint upon his/her freedom to choose.

The main reasons for requiring written consent are presumably twofold (though they are never made explicit)--they are a means to audit the conduct of investigators and as evidence they afford investigators legal protection. They may also afford participants similar legal protection if also signed by the investigator or an authorized representative and preferably attested to by a third party.

It appears that no consideration is given as to whether the legal protection afforded by written consent should override a participant's willingness of free choice to participate without giving written consent. We note now, and shall discuss below, the fact that some other forms of documentation, such as testifying to the fact that a given person or corporate body gave informed consent, do not similarly constrain choice while affording the participant as full protection.

The choice among options, e.g., written consent, testimonial/warrant, and testimonial cum complainant notice discussed next, involve choices among who deserves protection from what, who is to be regulated, and how is regulation by consent to take place. Specifically we shall compare each of the

three modes of documenting informed consent in terms of their grant of freedom of choice, regulation by audit and complainant mobilization, and protection through affording legal evidence.

Written Informed Consent. The HEW Code of Federal Regulations (45 CFR 46.10) specifies the actual procedures to be utilized in obtaining "legally effective informed consent" by documentation. The documentation of informed consent must employ one of three forms:

- 1). "Provision of a written consent document embodying all of the basic elements of informed consent. This may be read to the subject or to his legally authorized representative, but in any event he or his legally authorized representative must be given adequate opportunity to read it. This document is to be signed by the subject or his legally authorized representative. Sample copies of the consent form as approved by the Board are to be retained in its records." (45 CFR 46.10: (a))
- 2). "Provision of a 'short form' written consent document indicating that the basic elements of informed consent have been presented orally to the subject or his legally authorized representative. Written summaries of what is to be said to the patient are to be approved by the Board. The short form is to be signed by the subject or his legally authorized representative and by an auditor witness to the oral presentation and to the subject's signature. A copy of the approved summary, annotated to show any additions, is to be signed by the persons officially obtaining the consent and by the auditor witness. Sample copies of the consent form and of the summaries as approved by the Board are to be retained in its records." (45 CFR 46.10: (b))
- 3). "Modification of either of the primary procedures outlined in paragraphs (a) and (b) of this section. Granting of permission to use modified procedures imposes additional responsibility upon the Board and the institution to establish: (1) that the risk to the subject is minimal, (2) that use of either of the primary procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance, and (3) that any reasonable alternative means for obtaining these objectives would be less advantageous to the subjects. The Board's reasons for permitting the use of the modified procedures must be individually and specifically documented in the minutes and in reports of the Board's actions to the files of the institution. All such modifications should be regularly reconsidered as a function of continuing review and as required for annual review, with documentation of reaffirmation, revision, or discontinuation, as appropriate." (45 CFR 46.10: (c))

Setting aside the provision of a modified procedure, it should be noted that there are several significant omissions in the written informed consent attested to by the research subject and/or others. Brief mention is made of each of these since we shall wish to compare several modes of subject and investigator protection later.

1). No provision is made for advising subjects or their representatives as to who retains the signature document, for what purpose, and of how it will be protected and used.

2). No provision is made for documentation of refusal to grant written and informed consent and of how that is to be protected and used.

3). No provision is made for documentation of withdrawal of informed consent once given and what rights, if any, the person has in information provided prior to that point.

4). No provision is made for the document to be signed by the person officially obtaining the informed consent in all options (altogether absent except in the abbreviated form of consent) or for location, date, and time that consent was obtained.

5). The provisions are silent on the matter of who retains the signed informed consent document. The investigator is not obligated to provide a copy to consenting persons and if only a single copy is refused, as appears to be the case from the language of the regulations (e.g., 45 CFR 46.10: (a) "This document is to be signed by the subject or his legally authorized representative. Sample copies of the consent form (*italics mine*) as approved by the Board are to be retained in its records.") it apparently is to be retained in the principal investigator's files for purposes of audit.

6). No provision is made to advise persons who will have access to

to the signature document and for what purposes. Under federal law, federal auditors may have access to such documents for purposes of audit. Their powers probably include a right to inquire of persons whose informed consent was obtained or consent refused, i.e., whether or not specific procedures were accomplished or specific information obtained, though not what a person said or how he behaved. The extent of auditor powers over information on informed consent is a matter for further clarification, however, and perhaps provision should be made to limit it, should they appear to be overly broad powers that intrude upon privacy and thereby fail to adequately protect both subjects and investigators. The proposed LEAA regulatory code stipulates that revelation of all "research and statistical information identifiable to a private person may be revealed on a 'need-to-know basis only to:

"a) Officers, employees and subcontractors of the recipient of assistance;

"b) LEAA staff; and

"c) Persons or organizations for research or statistical purposes.

Information may only be transferred for such purposes upon a clear demonstration that the standards of Section 22.26 have been met, except that when information is transferred to persons other than LEAA or project staff, that the transfers shall have been conditioned on compliance with a Section 22.24 agreement."

(28 CFR 22.21)

The above provision makes explicit that for all LEAA grants at least three categories of persons or organizations may have access to information provided by informed consent without the explicit consent of the participant provided that there is a "need-to-know." While there are rules and precedents

that govern "need-to-know" and the proposed LEAA code provides rather full and explicit guarantees of protection of the information through the confidentiality certificate, transfer agreement, and sanctions provisions, it seems possible that since auditors or staff persons are not covered in the regulations by the provision for immunity from legal process, some possibilities for compulsory disclosure still exist. In any case, federal regulations cannot preclude federal auditor powers, absent explicit legislative restriction on such powers. There would seem to be good reason to seek to restrict such powers, at least to protect any confidential identifiable information so obtained from authorized or compulsory disclosure.

At the same time, any regulations should make explicit the classes of persons, including those of the sponsoring institution, that shall have access to confidential information and the conditions pertaining thereto. Should Institutional Review Boards, for example, in connection with their review and regulatory powers have the right to information on who did and did not grant informed consent and whether the provisions of protection and confidence were fulfilled by the principal investigators? Given their powers and responsibilities for approving projects and continuing review (45 CFR 46.6 and 46.7: (g)) they may have a right to such access; if so, it should be clearly stipulated by regulation.

Special Features of Documenting Informed Consent by Signature. A number of special problems arise in documenting informed consent by requiring all consenting persons or their legally authorized representative to attest to their consent by signature on the written consent form. These special problems need not arise for some other forms of consent.

Documenting informed consent by participant signature (written consent) makes the unique identity of each participant known to an investigator, even when the object of all other procedures is to insure anonymity to all participants. Having information on the unique identity of participants creates ipso facto (ipso jure) a problem of protection where confidentiality characterizes the information.

There are three principle ways that investigators procedurally protect from disclosure the identity of participants and the information they provide by selecting different accessioning and eliciting procedures.

First, investigators can protect the identifiability of information by the manner in which they procedurally accession participants. Procedures for accessioning participants range from accessioning subjects by techniques that make it impossible for anyone other than the subject to know he/she is a participant--the anonymous participant--to procedures that provide for their unique identification. Regardless of what accessioning procedure is used, however, the requirement for documentation of informed consent by signature makes it altogether impossible to have anonymous participants. The requirement is a burdensome restriction since it forces investigators to protect the anonymity of participants in research when disclosure of their identity as participants is in itself potentially harmful and the investigator could protect by anonymous participation.

Second, the procedure for eliciting information can be anonymous. Under these conditions the documented informed consent by signature poses no problem of uniquely identifiable information. Whenever there is no reason why the unique identity of participants should not be made public or when it is indeed public knowledge, documentation by signature provides protection to investigators

in accessioning participants and they may still protect anonymity by their collection procedure. There are, however, distinct limitations to anonymous data collection techniques since they preclude certain types of study design and forms of analysis.

Third, when both the accessioning and elicitation procedures provide for unique identification, protection can be afforded by separating both the documentation of informed consent by signature and any other identifiers that may permit unique identification of information from the information itself.

Whenever consent is documented by signature, however, the evidentiary problems in separation are compounded so long as one is required to maintain the documentation of consent.

It is unfortunately the case that modes of accessioning participants in behavioral science research often must provide for knowledge of one or more identifiers that can lead to unique identification. For example, if one wishes to have a random selection of households or persons in the United States, one must obtain information on certain identifiers such as an address and on household characteristics to select a respondent, e.g., "head of household." Since in a given unit at a given address, the head of household is often a unique identifier, e.g., in one person households, a single identifier can provide unique identification.

Yet it is well to bear in mind that in much behavioral science research, our interest does not lie in these identifiers as a means of identifying unique individuals but in social aggregates. The identifying information is incidental to the participant accessioning or data collection procedure. To return to our examples, we do not select an address or a phone number by random means to know whom we are uniquely getting information from but to

insure that in the aggregate we are getting information from participants who represent classes of participants or who in the aggregate will describe the universe of participants in which we are interested within a given range of error of estimation.

Although our procedures then may make it necessary to collect information that falls in the class of identifiers that individually or collectively may lead to unique identification, any procedure of securing consent should not invariably coerce the collection of a unique identifier such as a signature. Ordinarily unique identifiers should not be obtained in behavioral science inquiry unless they are essential to the inquiry or its design. Since they usually are not essential, documentary evidence of unique identity is burdensome since it increases risk of disclosure and correlatively the need for protection of confidentiality. That risk of course can be balanced by forms of legal protection, but the only certain way to protect is not to document accessioning participants and their informed consent with unique identification procedures.

When an investigator seeks to protect participants by anonymous means of accessioning participants or data collection, although informed consent should be obtained, the requirement of documentation of that consent by participant signature should be waived altogether. The other requirements of abbreviated consent, moreover, should be obviated, particularly the provision "of considerable immediate importance," since that is rarely applicable in behavioral science inquiry.

The written informed consent is not altogether practical in using some techniques of data gathering. The consent to enter a private place to conduct an interview may be necessary before any written informed consent could be obtained, for example. Such field setting difficulties should be sufficient

grounds for waiver of some requirements of consent.

As noted previously, organizational behavior research raises questions about the obligation to secure written informed consent. Where evaluation research is a matter of formal contract, the consent of employees may not be required, e.g. observation of them at work. Likewise documentary research poses special problems, particularly in matching records. Apart from the fact that it is impractical to obtain written and informed consent from the deceased or from those who have moved or otherwise cannot be located, the risk of disclosure or harm in their use ordinarily is no greater than that arising from their retention by the original data source. With guarantees of confidentiality, risk should ordinarily be so low as to preclude requiring any form of consent for the use of many kinds of records.

Informed consent that is written and documented by signature can serve to constrain refusals to respond or withdraw from participation. There is some evidence that signing any consent document makes it more difficult to break a trust relationship or agreement. The basic fiduciary element in any contract is not that easily broken--no matter how fragile it may seem in a modern world--and some participants will find it harder to break the relationship of commitment than others. It is well to remember that to bind investigators to do right may also bind their subjects so that they are less rather than more free. An informed and documented consent has such elements.

Subjects or participants, moreover, often are willing to consent but not sign. Signatures arouse suspicion and affect the willingness to participate. Whenever a unique identifier is not essential to the research study, it seems burdensome to require a signed or third party attestation procedure since on the average it will reduce the participation rate (a source of error) and may affect the validity and reliability of information (other

sources of error). Above all, it becomes more difficult to control and measure error in estimation for aggregates.

Finally we shall discuss some problems that arise from the requirements for a modification of the written informed and signed consent procedures.⁴ The requirements that an abbreviated procedure meet the test of that "either of the primary procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance, and that any reasonable alternative means for attaining these objectives would be less advantageous to the subjects" (45 CFR 46.10:(c)2(3)) derive, it would seem, from the bio-medical Human Subject model (where they surely may be appropriate) rather than from a behavioral science model. We call attention here to their inappropriateness when one or more of these conditions prevail, a condition of common occurrence in behavioral science inquiry. First, often proof is lacking that the primary procedure would invalidate the objectives of the study in the particular case of which the application for approval is an example. Second, the objectives of behavioral science research are only rarely of "considerable immediate importance." And, third, since the means used often are of no particular advantage to subjects, the consideration of alternatives is usually inapplicable. Indeed, the only condition of the modification procedure that is ordinarily applicable to behavioral science research is "that the risk of any subject is minimal" (45 CFR 46.10:(c)-1). It should ordinarily, therefore, be the only condition required for modification. Other conditions that are not stipulated seem more applicable in permitting modification of written informed consent procedures in behavioral science inquiry such as permission to modify when the need for information on unique identifiers is absent or they do not need to be retained after the participant is located for the

data collection phase of the inquiry.

Investigator's Signed Testimonial or Warrant of Informed Consent. We have noted that the signed written informed consent procedure currently governing HEW sponsored research lacks some protections for subjects or participants in research. Some of these would be added to current procedures but others cannot be added without changing its form to that of an investigator testimonial or warrant. It is to this form we now turn.

Both participants and investigators require some form of protection in behavioral science research. In the matter of informed consent participants must be informed particularly of risks and/or benefits so that they may make a free choice about participation. Investigators must be protected from being compelled to be agents of harm toward subjects as a consequence of their participation in the research. The consent form should do both these things but on balance insure the rights of participants more than those of investigators should choice among them be necessary. Nevertheless, a procedure which more nearly balances both participant and investigator rights and their protection should be optimal. The investigator's testimonial or warrant of informed consent should be preferred to the signed written informed consent on the following grounds.

In the investigator's written testimonial or warrant of informed consent, the investigator or his/her agent warrants that a person or corporate body or their representatives have been advised of the required elements in securing their informed consent and it was granted. The basic elements are these:

- 1) A written document that is approved by the Institutional Review Board embodying all of the basic elements of informed consent;
- 2) A statement of whether the document was read by the named participant and/or his/her named legally authorized representative or

read to either party by the named investigator or a named auditor witness;

- 3) The name and address of the consenting party or legally authorized representative who consented or refused consent;
- 4) A statement of any additional conditions agreed upon and (at option) any modifications agreed to during the elicitation of informed consent;
- 5) A statement of whether any record is made providing unique identification as a matter of record as in visual or voice recording;
- 6) A statement of how the information is to be analyzed and disseminated and the information stored (perhaps optional if there is aggregative reporting and full protection for confidentiality of information--though the Institutional Review Board must grant such exemption);
- 7) If the principal investigator is not the person soliciting the form of the consent he/she shall be named as well as the institutional sponsor who also signs as the authorized representative (the authorized representative should have reasonable proof of his/her authorization and provide this identification in securing informed consent, but in any case shall be obligated to furnish reasonable proof in the course of eliciting informed consent if it is requested by any party to consent);
- 8) A statement of whether any legal protection is afforded the participant by this study such as a confidentiality certificate or by sanctions against misuse of information. Where no such protection is afforded the participant and it is concluded that

"more than ordinary" risk of harm is involved should confidence become public information, the participant must be advised that the investigator is not able to afford protection against compulsory disclosure; since tort remedies are possible for misuse of information, it is perhaps not necessary that the participant be advised of them;

- 9) Whether consent was granted or refused and whether there was withdrawal following consent (the participant permitting) should be recorded;
- 10) A copy signed and dated by the principal investigator (either as the party eliciting information or performing procedures or as granting a particular agent authority to do so) and by the representative authorized to secure consent or perform other procedures and by the participant or his/her legally authorized representative when consent is granted shall be given to all whose consent is elicited including those who refuse to grant consent as well as those who grant it. The form shall include the name and address of the institutional sponsor and of an authorized representative for the institution;
- 11) The investigator shall keep no record with unique or other identifiers when a subject refuses to grant consent or later withdraws it unless there is full legal protection against compulsory disclosure and misuse of information. Where informed consent is granted the investigator shall not refuse subjects to provide their signature of consent unless the participant has been advised there are specific risks of harm of which he/she is advised in securing informed consent. When an investigator retains a signed written informed

consent document there must be reasonable protection against disclosure of that evidence;

- 12) Where any procedure in the research intervention other than the elicitation of information is performed on the subject by other than the person eliciting information, there shall be a stipulation that the principal investigator agrees to provide full information on who performed such procedures at any time that the participant or his legally authorized representative requests. Moreover, the participant is entitled to information of the name and address of any person who had authorized access to confidential information and of unauthorized access, if known to the investigators. The investigator therefore is obligated to keep a record of all such interventions and who performed them insofar as they are specifically for purposes of the research only (some investigators are legally compelled to keep such records in any case);
- 13) No member of an Institutional Review Board shall have access to unique identifiers or uniquely identified information unless they enter an explicit agreement with the principal investigator to protect the confidentiality of such information and where applicable become subject to any provisions for sanctions against misuse or disclosure (28 CFR 22.29, for example);
- 14) When specifically requested, the principal investigator must provide information on the specific government agency sponsoring the research, its address, and the designated officer signing on its behalf.

The Investigator Written Testimonial or Warrant With Provision for Complaint. Although one may regard the testimonial or warrant form as

providing sufficient information and a legal document for formal litigation, provision may and perhaps should, be made to provide for less formal modes of adjudication of complaint. In any case, whenever the procedure involves actual or potential risk of harm, participants should be specifically advised of that "right" or "possibility" including the following:

- 1) A statement that if they wish to lodge a complaint or secure further information on the particular inquiry (e.g., pending further participation) they are given the following information:
- 2) The identity of the investigator and/or the legally authorized representative who secured consent and of the institutional sponsor and its representative as the agents who should be contacted unless the Institutional Review Board chooses to designate itself or other agent to secure such complaints. Complainant rights are more fully protected when the complaint is lodged with a disinterested party. Principal investigators and their agents are not disinterested parties. Therefore, unless it is unduly burdensome, an Institutional Review Board or its agents should receive such complaints and provide for some means of their review and adjudication (including, of course, involving principal investigators). The institutional sponsor is not always a disinterested party and for some special kinds of research, the government sponsor of the research may chose to require that it be designated the agent to whom such complaints should be directed. In any case, all investigators or their agents must provide such information on specific request as required in the testimonial form. We would note parenthetically that in all cases there should be some means provided for dealing with complaints whether of principal

investigators, institutional sponsors or government sponsors of research.

- 3) There shall be a record made and retained for a reasonable period of time following the conclusion of the inquiry of all such complaints received and any actions taken thereon. Such records when kept by principal investigators, shall be accessible to the Institutional Review Board and at least some record of them and actions taken on them kept in its files.

If one intends to protect a subject's right to protection in research inquiry, it seems essential that the complaint procedure be followed whether or not consent is documented by the written and participant signed informed consent of the testimonial or warrant signed consent form. Moreover, written notice of when complaint can be lodged should be the minimum provided when-ever informed consent must be secured. The reason for this seems obvious enough. Most participants may either err in this acquisition of information about whom they are dealing with in the consent procedure or fail to retain or recall the requisite information essential to lodging a complaint. The obligation in all cases should fall on investigators to provide information documenting how complaint can be lodged in the form: "if for any reason you wish to know more about this study or complain to others about what was done to you, call or write to _____." The form of notice should in all cases be intelligible to all literate persons.

Should only the complaint form be required, provision should also be made within the written form to advise the participant that information on the name and address of any person who had contact with the participant in performing any procedure connected with the research intervention or had authorized access to any confidential information pertaining thereto or

of unauthorized access, if known, will be provided on request. There likewise should be an obligation to provide information identifying the government sponsor on specific request

Comparison of Modes for Documenting Informed Consent. We turn now to compare the relative advantages and disadvantages of the presently authorized mode of documenting informed consent and the proposed model. Chart I summarizes these comparisons. Little comment seems called for since the comparisons should be obvious to the reader. Before turning to some summary observations and conclusions derived from the comparisons in Chart I, we return to review the prototypical bio-medical Human Subject model and the prototypical behavioral science model as they bear upon these comparisons.

In the choice of models for securing informed consent it is well to bear in mind that the prototypical bio-medical model and the prototypical behavioral science model have both different "harm" probabilities and different harm points in the research process. Quite typically the bio-medical model involves some risk of harm both from administering the experimental or treatment procedure or by delayed effect and such effects are ordinarily mentioned throughout the period of research inquiry. Although similar conditions prevail in some behavioral science inquiry (more likely so in research by psychologists than others) and they are more likely to arise in the use of some techniques (e.g., social or psychological experiments or longitudinal studies), the prototypical behavioral science model involves virtually no risk of harm from or during the data collection phase and minimal risk from the data processing and analysis phase. The behavioral science model, moreover, incorporates corporate as well as person actors. Risk to person or corporate actors in a research inquiry

CHART I

A Comparison of Three Document Modes for Eliciting Informed Consent in Research

Provision Made for	Mode of Documentation		
	Written with Participant Signed Consent ¹	Written Investigator Signed Testimonial or Warrant of Consent	Investigator Written and Signed Notice to Complainant
Free Choice to document consent procedure by signature	Participant not free to choose only	Investigator and Participant not free to choose ²	Investigator not free to choose
Unique identification required apart from signature	NOT REQUIRED	Both required apart from signature	NOT REQUIRED
Documented or other evidence of unique identification	1) Signature of participant only ³ 2) Possible fingerprints of both 3) Handwriting required of investigator for any amendment 4) Possible signature and fingerprints from auditor witness	1) Signature of both 2) Investigator lacks participants fingerprints 3) Handwriting required of investigator for any amendment 4) No auditor witness necessary	1) Signature of PI only 2) PI or representative fingerprints possible 3) No handwriting if separate from other forms 4) No auditor witness necessary

CHART I (Continued)

Provision of Complainant Information	No documentation or written notice required	Information on unique identity of PI and his/her agent when applicable provided but no notice provided	Formal notice and information on where complaint may be lodged provided
Provision for documentation of refusal	None	Required unless excepted	None
Provision for documenting informing procedure	None required	Whom read by and for	None required
Provision for documenting representative or auditor witness	Auditor witness only documented	Representative documented; no auditor witness required	Not documented
Written statement of required elements for being informed	Required	Required	Not required
Written statement of additional agreement	Not Required	Required	Not required
Written disclosure of Unique Identification Retained and Protection Provided for Uniquely Identifiable Information	Not Required	Required	Inapplicable

CHART I (Continued)

Possession of Documentation	By PI only (implied)	By Participant or both participant and Investigator	By Participant Only
Availability of Information on Who Performed Procedures Other than Eliciting Consent	Not Specifically Provided	Specific Provision Made	Specific Provision made
Access to Unique Identifiers or Information Uniquely Identified by Institutional Review Board	Rights of IRB not clearly defined but has broad review powers	Restricted to Explicit Agreement to provide confidential information	Inapplicable
Provision for Identifying Government Sponsor	None made since obliged to answer questions about procedure only	Obligated to provide on request only	Obligated to provide on request only

Footnotes

1. These comparisons are made using the present CFR. They are not all integral to the Written with Participant Signature documentation form. The form can be modified for some but not all comparison criteria.
2. An optional form might require only that the investigator document by signature that informed consent was elicited from a particular participant. This optional form probably is appropriate for some corporate actors and for much survey research when written documentation is required.
3. We make note of the fact that fingerprints are more difficult of recovery from paper than some other objects but much depends on conditions for both the paper and signatory. It is possible that anxiety and other factors attendant upon obtaining signed consent are more favorable to their recovery than is ordinarily the case and more likely for participants than investigators or their agents.

ordinarily attends the disclosure of confidential information, particularly the risk from compulsory disclosure. This form of harm, should it arise, usually follows publication or the dissemination of information when all contact with the subject is terminated. Indeed, given the high residential mobility of participants in much behavioral science inquiry, participants are not easily followed nor located.

The comparisons provided in the preceding discussion and in Chart I call attention to forms of documentation and protection that would seemingly be essential to documenting informed consent yet are not provided in current federal regulations (45 CFR 46). Although some of these could be added to the present form of "written informed consent" others when added would transform it into either a testimonial or warrant document or to a formal agreement signed by both parties. Moreover, it should be clear that there are many different combinations possible of the elements in Chart I and the elements of information necessary to being informed. The specific concept to be applied to the form of documentation is of the barest consequences.

Comparison also will make apparent that the currently approved regulations for documentation are balanced in favor of providing protection for investigators rather than for participants. They also leave both participants and investigators vulnerable and unprotected in matters of confidentiality of information. The investigator testimonial form moves toward fuller guarantees for both participants and investigators, though on balance it may protect more the rights of participants. Without more adequate legal protection against misuse and explicit provision for provision against compulsory disclosure, however, all forms of documented consent make both participants and investigators vulnerable to harm through the disclosure of information. It is to this matter--the legal protection of confiden-

tiality--that we shall turn in Sections III and IV.

Feedback on Procedure and Participant Satisfaction.

Some bio-medical and behavioral science inquiries make provision for feedback from participants on the procedures used and their satisfaction or dissatisfaction with being a participant either during the procedures or at their termination. The question should be asked whether feedback should ordinarily be required as part of any research procedure. There are persuasive arguments in its favor but some to the contrary as well.

Feedback can be of considerable utility to both participants and investigators. Investigators may well learn how to reduce risk from harm or how to increase participants' benefits by systematically eliciting feedback. The more exploratory the procedure or the greater the risk of harm from its use, the more Institutional Review Boards should consider making feedback an essential element of "procedure." Such feedback should be refused whenever there is reason to believe that knowledge of it will make corrective action possible to protect the participant from further harm or to "undo" harm.

Yet, there are reasons why it should not be required or even to prohibit its use. Investigators, for example, may seek feedback to "cool" participants from legitimate complaint or they may use it in other deceptive ways. Even though investigators do not intend these effects, whenever feedback has a reasonable likelihood of doing so for a reasonable number of persons "at risk," its use should be prohibited or circumscribed so as to avoid effects that are not in the interest of the participant.

Participant Rights to Information

There are important and largely unexplored issues about the rights of participants to confidential or other information that has been secured from them by informed consent for purposes of scientific inquiry. Apart from such rights as Federal law provides--e.g., where information given to a government sponsor of research, a participant has the right to review all information that retains unique identification and to correct the record--the issues are far from clearly formulated, much less resolved. There are many difficult questions that will arise in discussing the matter of participant rights to information and we shall not review them here. For example, given the right to review information that is uniquely identified and to correct that record, is it reasonable to conclude that subjects can correct many matters of observation and recording that refer to their behavior, attitudes, or other research investigator recorded information, or does it apply only to those items of information that can be validated independently of the subject's correction?

Matters of correcting research records apart, participants should have a right to request a copy of all information where unique identification is retained so long as its disclosure does not invade the privacy of other rights of any others referred to in that record. Both the proposed procedures for protecting the identity of human subjects of DHEW (42 CFR 2a7:(b)) and of LEAA (28 CFR 22.23:(4)) provide for the release of confidential information with the consent of the participant, but they do not unequivocally grant the participant the right to review or request a record of all information that is retained with unique identification. There perhaps are some limits on the extent to which participants may request information that remains uniquely identifiable as, for instance, were there a strong presumption

that knowing it would cause the person considerable harm. A more difficult question, however, is whether the participant is entitled only to that information given with the participant's informed consent or to all information on the participant in the records in a uniquely identifiable form. Often in behavioral science studies, information is secured on transactions among persons or corporate actors. Where the informed consent of others was involved in securing the information, a participant's rights are less clear. On the one hand, any confidential information, regardless of its original source, is potentially damaging on disclosure and any participant should have a right to know what is in the record, but on the other hand, persons who gave such information with a promise of confidentiality have a right to have the information kept confidential. The teacher who provides information on pupils or the wife who provides information on the husband (and vice versa in the above illustration) create a special case where rights to information are hopelessly intertwined and where the knowledge that each would have access to all information provided by the others obviates all forms of research except that of the public forum. In short, without limits on the right of participants to information that is uniquely identified, a right to request all of the information that is a matter of record could well have a chilling effect on all research where confidential information is secured about a participant from anyone other than the participant.

The Rights of Investigators to Information Secured on Promise of Confidentiality.

Whether and what rights investigators have to information that has been secured by informed consent without explicit forms of legal protection is far from clear. They obviously possess those rights in the information that are

matters of informed consent and contract--to use it for the explicitly stated purposes of research and all related interventions explicitly provided for as matters of agreement. But that right is not exclusive, subject as already noted to rights of those who provide the information. Where a promise of confidentiality is explicitly provided for in obtaining informed consent, investigators should have the exclusive right and duty to protect the information subject only to the rights of those who consented to give the information. They, of course, have a right to use that information only so long as they intend no harm in using it.

Transfer of Confidential Information to Other Investigators. Among the many other matters at issue in subject and investigator rights is the question of whether an investigator may share information that has unique identifiers with other investigators to whom consent was not originally given. This matter arises where confidential records have been obtained and where there was no prior agreement to use them for a given inquiry. Indeed, any more or less general provision giving an investigator the right to permit access to the confidential information for purposes of research, other than that for which informed consent is being secured, will generally be so vague and incomplete as to lack the very elements considered basic to informed consent (Goldstein, 1969). Should this mean then that except where informed consent is originally secured for one or more specific projects, or where a subject is subsequently contacted and informed consent secured for each subsequent project using the information, no other research access should be permitted? That rule would seem to be unusually burdensome, given the high cost of much behavioral science inquiry and the cost attendant upon building up time series from individual data.

Where the risk from subsequent use of the information provided by informed

consent can arise solely from its public disclosure, and where there is legal protection against compulsory disclosure and strong sanctions against its misuse, investigators should have rights to transfer confidential information provided the same protection is afforded on transfer. That right should extend to its use not only for similar and related projects but to unrelated ones that in the judgment of the investigator or/and institutional or government sponsors are in the public interest of free scientific inquiry. The transfer of such information should not be left entirely to custom, however, and should be protected through federal regulation. The proposed regulations by LEAA set forth the major elements for any information transfer agreement (28 CFR 22.23 & 22.26).

The major elements of a request for transfer of information should include the following (28 CFR 22.26:(b)):

. . . the general objectives of the project for which information is specifically requested, and specifically justify the need for such information in identifiable form. The request shall also indicate and provide justification for the conclusion:

(1) That conduct of the project will not, either directly or indirectly, cause legal, economic, physical, or social harm to individuals whose identification is revealed in the transfer of information.

(2) That conduct of the project as designed would not be expected to have a detrimental effect on overall future research or statistical efforts of the Federal or State government.

The information transfer agreement should be formally executed and should make provision for at least the following minimum information stipulated in the proposed LEAA regulations (28 CFR 22.24):

(a) Information identifiable to a private individual will be used only for the purposes stated in the transfer agreement.

(b) Information identifiable to a private individual will not be revealed to any person for any purpose except where

(1) The information has been included in research findings (and/or data bases) and is revealed on a need-to-know basis

for research or statistical purposes, provided that such transfer is approved by the person providing information under the agreement, or

(2) is authorized under 22.24(e).

(c) Knowingly or willfully using or disseminating information contrary to the provisions of the agreement, shall constitute a violation of these regulations punishable in accordance with the Act.

(d) Adequate administrative and physical precautions will be taken to assure security of information obtained for such purpose.

(e) Access to information will be limited to those employees or subcontractors having a need therefore in connection with performance of the activity for which obtained, and that such persons shall be advised of, and agree to comply with these regulations.

(f) Project plans will be designed to preserve anonymity of private persons to whom information relates, including, where appropriate, required name-stripping and/or coding of data or other similar procedures.

(g) Project findings and reports prepared for dissemination, will not contain information which can reasonably be expected to be identifiable to a private individual.

(h) Information identifiable to a private individual (obtained in accordance with this agreement) will, unless otherwise agreed upon, be returned upon completion of the project for which obtained.

These proposed regulations clearly provide that all sanctions, including fines, obtain for all investigators and their employees who have access to information by transfer agreement. Whether the provisions of protection from compulsory disclosure also apply is not altogether clear in the LEAA regulations but were a transfer agreement to be legally authorized under the proposed HEW regulations for protecting the identity of subjects (42 CFR 2a), such protection would seemingly apply to the transfer agreement as well since: "The protection afforded by a Confidentiality Certificate is permanent with respect to subjects who participated in research during

any time the authorization was in effect" (42 CFR 2a8:(c)).

Cooperative Activities to Develop Confidential Information. The DHEW regulations currently in effect make provision for cooperative activities " . . . which involve institutions in addition to the grantee or prime contractor (such as a contractor under a grantee or a subcontractor under a prime contractor)." (45 CFR 46.16). They further provide that: "If in such instances, the grantee or prime contractor obtains access to all or some of the subjects involved through one or more cooperating institutions, the basic DHEW policy applies and the grantee or prime contractor remains responsible for safeguarding the rights and welfare of the subjects" (45 CFR 46.16).

The obligation which falls on the grantee or prime contractor to safeguard the rights and welfare of subjects will hardly guarantee subjects protection when, as is now the case, there are no stringent sanctions against unauthorized disclosure or misuse of the information. Prime contractors now have no specific sanctions available to deter misuse nor are there provisions against compulsory disclosure. One must grant that it is surprising that despite considerable subcontracting in behavioral science research, few situations have arisen where sanctions are appropriate. Yet there have been somewhat more situations where protection against compulsory disclosure seemed essential, as in the negative income tax experiments in New Jersey.

III. CONFIDENTIALITY

Confidentiality is the communication in confidence of private matters. It involves a fiduciary responsibility--a pledge or promise to hold privileged or otherwise keep secret communications about private matters. It also involves a promise of protection and implies the capacity to keep matters communicated in confidence from disclosure by the confidant or others.

Both fiduciary and protection obligations come into question when investigators pledge confidentiality in behavioral science research. Investigators often are caught in a dilemma that a pledge of confidence is necessary to secure valid and reliable information but they lack the legal right of privileged communication and the sanctions of tort law are inadequate protection against misuse or disclosure by others to whom the responsibility for confidentiality must necessarily be entrusted. Viewed another way, many investigators are well aware of the fact that organized behavioral science inquiry involves a chain of confidence and they are personally and morally committed to maintaining that confidentiality even at the risk of loss to themselves. They lack, however, sufficient knowledge about their vulnerability to disclosure and the weakness of the protection afforded them in promising confidentiality. Many behavioral science investigators, therefore, enter into a pledge of confidence in good faith but their faith rests on a weak societal foundation whose dimensions they know not.

Requirements for Pledge of Confidentiality. On its face, pledges of confidentiality should not be extended by investigators for information provided them except when it concerns private matters. What is a private matter is defined at law; yet it hardly bears noting that most people are unaware of what are private, privileged and public matters at law; ultimately the

courts will decide if a particular matter at issue is private, privileged or public. And that is of little help either to investigators or their participants whose informed consent is being elicited. There is a reasonably strong basis for argument that communication between investigators and subjects should be privileged whether or not there was an express or implied promise by the investigator to the participant that the information provided will be treated as confidential. First, most subjects become accessible to inquiry because investigators approach them to seek their cooperation; while confidentiality may be promised, when it is not, unless they are expressly advised that what they say can be told to anyone, they invariably assume confidentiality. Moreover, even when they volunteer to participate, they ordinarily assume that implies confidentiality as well. Most participants, moreover, are unaware of what is implied in confidentiality even when they are advised of some risks. Likewise, the method used to acquire information may not make it easy to promise confidentiality since others may be privy to the same matters. That should not leave the particular instance from protection, however. I note parenthetically that a participant may disclose the same information to a friend, a journalist, and a behavioral scientist with the expectation that all will regard it as confidential and without any explicit promise of confidentiality, a complicating feature in much behavioral science inquiry. Unlike much biomedical inquiry, where a particular piece of information is unlikely to become available except as a consequence of the research intervention, behavioral scientists seek to acquire information to which many others are privy but in the expectation that it will be regarded as confidential. Needless to say, full protection of information on participants by investigators is possible when,

and only when, the investigator and the participant uniquely share a given matter as "private". That is, we suspect, rarely the case so that participants are not fully protected against disclosure of information they share with investigators but protected only from disclosure by that source. From the perspective of private persons (both person and corporate actors) in our society, whatever they regard as private matters in giving confidence should be treated as a confidential matter in research regardless of the status of law, i.e., there should be an absolute privilege. Yet it is unlikely that the society will grant an absolute privilege since that would cover a confidence that one was about to commit a heinous crime such as an assassination of a public official. While at law such relationships may need to be conditionally privileged, the conditions should be relatively few if one is to recognize that most people respond to a guarantee of confidentiality with their definition of what is confidential and we should ordinarily be prepared to protect those matters as well since they are important to them.

Yet, from the perspective of the public interest, there may be other reasons why investigators should not be given a simple license to promise confidentiality in exchange for information or compliance with an intervention in research. The government and institutional sponsors, as well as investigators, may wish to categorically prohibit or circumscribe the investigator's right to pledge confidentiality for public behavior. Seemingly there is no reason why they should not. Yet often access to public behavior must be obtained or the behavior of public officials or employees is being investigated and these become possible only through a promise of confidentiality.

Conditionally, it might be argued that investigators have no right to promise confidentiality for information on illegal conduct. Were that so, much behavioral science inquiry that leads to an understanding of illegality and its regulation by law and custom would not be possible. Indeed, it might be argued that conditions on confidence or privileged communication in research should generally restrict neither substance nor procedure in inquiry unless it is so clearly and substantially damaging to the public interest as to be stipulated by specific exclusion.

Given full protection of confidentiality in research, questions of its use might well be left unregulated by other than the investigator were it not for two matters. First, the capacity to protect confidentiality is never absolute and therefore damage may result. For that reason some assessment of potential harm and its seriousness and the capacity to protect confidentiality must come into consideration in permitting investigators to promise it. Second, the privilege of communication opens the door to abuse of privilege. Investigators may seek to acquire more information than is necessary to the particular inquiry to meet their own needs or requirements rather than those of the participants or the larger public interest in research. Some regulation is necessary to protect both private persons and the public interest against unnecessary intrusion into private matters. In practice, it will be difficult to regulate investigators except by prohibition of a pledge of confidence given the difficulty of deciding what information is essential to the inquiry on the one hand and the fact that extraneous confidential information is offered by participants on the other. To refuse to protect participants who offer what is regarded as extraneous information seems arbitrary and not in their interest, given

what for many must be a very limited understanding of what lies within and what lies without the approved domain.

The major means for regulating the promise of confidentiality is to require that it not be utilized when there is some alternate means that will permit the acquisition of information while protecting the anonymity of participants from everyone, including the investigators. Absent that possibility, whenever possible, restriction should be imposed on the number of persons that may be privy to private matters and the length of time that uniquely identified information is accessible for disclosure. Yet even these matters are vulnerable as we have already noted, e.g., to testimony when physical evidence is destroyed but testimonial evidence remains viable.

In brief, then, a pledge of confidentiality seems essential whenever (1) participants regard it as a condition of providing essential information, whether or not at law it is a private matter; (2) whenever the information cannot be elicited and usefully analyzed with the participants remaining anonymous; and whenever the pledge is not clearly substantially damaging the collective or public interest. Correlatively, no promise of confidentiality should be given or required when there is no possibility for personal harm on disclosure of information or when the objectives of the study can be accomplished by strictly anonymous procedures. Whenever one restricts the chain of information, however, a promise of confidentiality must be given if there is risk of harm, though in the interest of protection from disclosure one may want to impose restrictions on acquisition of uniquely identifiable information by members of the chain.

Risks in Protection of Confidentiality. We have noted on numerous occasions that the major harm from behavioral science inquiry follows from the fact that information is socially powerful and damaging. When information

is used on private matters it may damage the interests or welfare of those to whom the information obtains. Now since the major risk from disclosure comes either from unauthorized or illegal misuse or from compulsory disclosure, harm will rarely occur if one is protected from these sources of disclosure. We turn to guaranteed forms of protection from these forms of disclosure in Section IV.

There are, nevertheless, some other problems related to protection from disclosure. Some of these arise from the nature of analysis and publication of results. For the most part, the analysis of data and publication of results in behavioral science inquiry is interested in aggregative information. There is thus little risk from disclosure apart from the eliciting and early processing of information unless for some reason the data are to be retained with unique identifiers for subsequent analysis. There are conditions under which one may do so apart from an interest in longitudinal or panel studies where uniquely identified individual or corporate actors are followed for extended periods of time. Some behavioral scientists have an interest in deviant case analysis. Correlation is always far from perfect and explanation is often incomplete and unsatisfactory. By returning to uniquely identifiable information with the opportunity to either add information to it or undertake a different form of analysis is extremely useful in trying to understand one's failures at explanation and in seeking leads for future inquiry. For these reasons the simple notion that one should eliminate unique identifiers as early as possible and not retain them so that information can be recaptured in terms of them seems often unwise.

The case history and case study techniques of inquiry and reporting are perhaps more vulnerable to disclosure of information than other forms of

analysis since they rely very much on retaining at least minimal unique identification for the information--separation of identifiers from the information but a capability for matching them. Both individual and corporate actor identities are at stake in such inquiry and in much evaluative research. Since often considerable information is published on a case basis, efforts are made to protect confidentiality by alteration of identifying characteristics, etc., but unless the investigator has been able to keep confidential the identities of all participants, alteration of identifiers may be a weak form of protection, given the limited knowledge one may have about what information others possess that might permit them to make a unique identification. Thus the more one disaggregates information or publishes particular case information, the greater the risk of disclosure. This is more likely to be true for corporate than individual actors as previously noted.

Types of Information to be Protected. There are four principal types of information that must be protected where a promise of confidentiality has been extended. Both participants and investigators must be protected against breach of confidentiality and both informant and investigator types of information must be protected if confidentiality is to be protected. The four types of information requiring protection are: (Nejelski and Peyser, 1975: B-37-41): (1) identity of the research subject; (2) contents of communications with a subject; (3) direct observations of subjects; and (4) work product.

(1) Identity of the research subject. The identity of individual and corporate actors depends both upon unique identifiers or a combination of identifiers that result in a unique identification. We have already discussed the status of unique identifiers such as fingerprints, voiceprints,

and photographs in behavioral science research and others may arise in biomedical inquiry. But an equally likely possibility for obtaining uniquely identified information is that a number of identifiers permit unique identification. There is, for example, in a given instance only one person who is of a given race, sex, age, income, and first name at a given apartment at a given address. I note that even fewer of these may be all that is necessary for a given unique identification in a given case, e.g., when there is a one person household at a given address that is the only household at that address. The problem of unique identification from a set of identifiers is problematic in the law of evidence so that what is uniquely identifiable information for behavioral scientists would not be regarded as meeting a sufficiency test for conclusion beyond a reasonable doubt at law. Yet the social world is not built on proof beyond a reasonable doubt, and much harm is done from the use of identifiers to converge toward unique identification. A formal system of law exists to protect against the doing of harm based on these forms of unique identification. Where unique identification is a possibility either because of unique identifiers or through the convergence of identifiers, and a promise or need for its protection exists, that information must be protected whether for an individual or a corporate actor.

(2) Contents of communications with a participant. Identifiers do not exist simply in the form of characteristics of individual or corporate actors but in the contents of their communications. Not uncommonly, knowing what specifically was disclosed to the investigator can lead to a unique identification, since that person, and that person only, was privy to that information or is responsible for it. As Nejelski notes, one reason for protecting the contents of communications from a source is the practical

difficulty "...in distinguishing between the information per se and information that would reasonably reveal the identity of the sources" (Nejelski and Peyser, 1975:B-39). We would think that the protection of the contents of communications might be more important for corporate than individual actors, but in the aggregate more individual than corporate actors might be so protected given their relative numbers in a population of participants.

(3) Direct observation of participants. Access to individual and corporate actors to observe their behavior, including illegal behavior, is essential to some kinds of inquiry. Those observations must be protected even when it has not been possible to obtain prior consent. Indeed, under some circumstances, as previously noted, one does not obtain consent for the observations but nevertheless records them. Thus the interviewer may be directed to record the race and sex of a person without direct inquiry or to record whether or not the subject appeared to be truthful or cooperative, and so on. Such observations are essential to improving the validity and reliability of behavioral science studies and should be protected.

(4) Investigator's work product. During the course of a research inquiry, much work product is produced that potentially would permit the disclosure of confidential information. Such product will never be disseminated and every effort will be made to insure that any final work product is free of the possibility of disclosure. Yet during the inquiry some work product may inevitably permit disclosure. We might, for example, have a computer output prepared that disaggregated information to a given level on the presumption that there is sufficient numbers of cases to do so and provide confidentiality. Yet when the output is examined, it is clear that unique identification is possible. One might not necessarily destroy that output immediately since there are ways to protect for that particular case (by simple

recombination, for example). Quite obviously since one cannot always guard in advance against the generation of work product that would permit disclosure of confidential information, it requires protection.

Types of Matters Where Disclosure Is Harmful. Social harm is a consequence of the actions of persons or collectivities against those who are harmed. While harm may occur when it is not intended as well as when it is intended, the disclosure of information results in harm whether or not it is intended whenever its consequences are harmful. At times the same information causes both harm and benefit. Unfortunately, one cannot always predict harmful or beneficial consequences and social prediction in many areas is at best subject to considerable error. What we must rely upon, therefore, is some notion of the potential for harm resulting from the disclosure of any piece of information, while recognizing that the disclosure of any information on private matters may be both harmful and beneficial.

We shall concern ourselves here only with those kinds of matters for which confidentiality must be promised because of their high potential for harm and low potential for benefit on disclosure. These are all matters on which behavioral science inquiry seems justified on grounds of public interest in the inquiry. They are only briefly enumerated since the argument should be clear from their enumeration:

1. Legal matters where the disclosure of information leads to a legal proceeding that is harmful to individual or corporate actors, including information from legally privileged communications and on violations of law leading to criminal, civil or administrative proceedings and sanctions.

2. Violations of organizational rules and regulations for which there are organizational sanctions against members.

3. Conduct that is stigmatized within the larger society or any group therein who have power to stigmatize conduct. The consequences of stigmatization may range from social exclusion and isolation to subtle forms of rejection and discrimination. Their potential for harm in any case may be considerable since stigma can affect the life-chances of individuals.

4. Performance and achievement measures or any related item that ordinarily is considered a private matter and its disclosure is regarded as violating the privacy of the actor.

5. Official or organizational secrets whose disclosure harms the participant by altering advantages or reducing benefits; their disclosure can be the cause of considerable damage.

These are but some of the major types of matters to which behavioral scientists can and do become privy in the course of inquiry and confidentiality must ordinarily be extended and protected if research on them is to continue. One must take note of the fact that considerable behavioral science inquiry has occurred on all of these matters without disclosure having become problematic. This is in large measure due to the integrity to all members and employees of the research community respecting fully any confidence given and to the openness and tolerance of the larger society toward that research community in withholding strong support for compulsory disclosure of such matters.

Exclusion of Protection for Information Acquired in Research. Both to constrain investigators from unduly intruding upon the privacy of persons whose confidence is obtained and to sustain the public interest in and right to information, some types of information, it is maintained, should be excluded from a promise of confidentiality and from protection if acquired. We have already dealt with the question of what might be excluded from a

promise of confidentiality and deal here with the question of whether there should be specific exclusion of any matters from legal forms of protection. The following matters that have been suggested for exemption from legal protection we shall maintain should be covered.

First, it is argued that information that lies outside the scope of the project should not be protected if the investigator elicits it and it is supplied by the participant. To leave that information unprotected, we suggest, is to punish participants for investigator misdoing.

Second, it is argued that the information participants provide that lies outside the investigator's promise of confidentiality should be left unprotected. Elsewhere we have suggested that it is difficult for participants to maintain those distinctions or even to perceive them. Moreover, they are not altogether in control of the activity which takes place when the investigator is present, particularly when consent has been given to enter a private place. Finally, persons may be damaged by such means as "guilt by association" or mere presence in a situation; the disclosure of such matters is unwarranted. We would suggest that participants should be fully protected in providing information once consent is given though investigators should be obligated to constrain them from offering any information that may be damaging to either party and that is not essential to the inquiry.

Third, any investigator acquires information even when subjects refuse or for some reason fail to participate or comply with what it is that the investigator seeks by inquiry, including a refusal to grant informed consent. We have already noted that even a refusal to grant informed consent may be damaging if known such as the disclosure of refusal of a member of a stigmatized group. Within total institutions or any institution that provides for

the compliance of their members with the inquiry, knowledge of failure to comply may be damaging and should be protected. Even within a total institutional setting when informed consent is obtained, such as in a prison, if the prisoner is released to appear for interview, for example, and fails to appear as agreed upon, should such information be protected on inquiry from the warden? These are no simple matters, but there should be no categorical exclusion of them from protection since in many, if not most, instances such protection should be afforded if behavioral science inquiry is to be sustained.

Indeed, one might make a reasonably compelling case that all information except that relating to potentially great harm at some future time should be protected from disclosure whether or not it was made a matter of confidence in securing informed consent. The reasons for this argument are several.

1. It is difficult to prove matters of what both subjects and investigators intended and understood and what and what not are the specific matters to be protected by agreement. More harm may be done from just such misunderstanding than would be done by full protection.

2. Where information is acquired because investigators exceeded their authority, participants should not be punished for their failures.

3. Since there is considerable variability among the participants in many studies in their levels of education and other skills, it is unreasonable that they will be able to specifically monitor what can and cannot be said or done with a given agreement.

4. Finally, absence of protection would likely generate patterned evasion on the part of investigators; much more attention would be given to excluding from the record information that was acquired lest it be considered extraneous and jeopardize the collection and retention of other information.

While such evasion might well be desirable in that it protects such information from disclosure, as a matter of record, it is still unprotected testimonial evidence. It may well affect the quality of information also, particularly since such screening must often be delegated to employees whose training in what to include and exclude is far from ideal.

There are conditions under which investigators should have full protection to keep information confidential that was acquired through explicit agreement in eliciting informed consent and that which was not even though the investigator is not in a position to protect against its disclosure. That is investigator warrant only that they keep confidential the information as they acquire it but not to guarantee anything other than that they will not be the source of disclosure. At the same time, some obligation falls upon the investigator to remind participants that others than the investigator may be the source of disclosure.

There is likely to be misunderstanding about what it is that investigators agree to and can protect. Investigators can protect only the information they acquire from their being an agent of disclosure. They can offer reasonably adequate guarantees of that protection only when they have legal protection against its compulsory disclosure and strong sanctions to protect it from illegal or unauthorized misuse. Yet participants and others are all too quick to conclude that what is being guaranteed is protection from its becoming public knowledge, forgetting that the only protection afforded is that the investigative agent agrees not to be an agent for its disclosure. This is no simple matter in securing and protecting informed consent since participants are all too easily confused in such matters and some protection must be afforded in the face of their possible confusion.

Let us return again to our elementary Human Subject model of a single investigator and single subject. There the acquisition of confidential information can be such that if it never has been or will be communicated to anyone else, or if in fact only the investigator acquires it through his intervention on the subject, protection against disclosure is a likely event. Yet if both subject and investigator share the information, either may be the agent of disclosure. The subject may even do so by sharing it in other modes of confidence including other agents who have and can afford protection. Yet in many situations where informed consent is elicited and confidentiality promised, it can apply only to the agent and disclosure from others is problematic. This is particularly true in some kinds of behavioral science research where the information derives from group settings or corporate actions. Whenever there is a third party to confidence, as is often the case in behavioral science inquiry, disclosure is possible without involving the agent investigator as the source of that harm. Paradoxically, he may be perceived to be the source of that disclosure when in fact he has been a protector and has no way of demonstrating that he has not been the agent of disclosure. The most that can be done in such instances is to demonstrate that there are no compelling or other reasons why he should have been its agent. Given the fact that disclosure is possible from more than one source in many kinds of behavioral science inquiry, it is incumbent upon investigators to advise persons from whom potentially harmful information is sought that the protection they offer--if legal or other protections are afforded--provides no guarantee against its disclosure by others. Clearly when investigators acquire confidential information in group settings or when third parties are present, they have an obligation to inform that anyone present other than the

investigator is a potential source of disclosure (unless they are covered by the investigator's privilege, e.g., as employees).

Types of Methods Presenting Special Problems for Protecting Confidentiality. We have observed many times that methods vary considerably in their capacity to provide anonymity in the eliciting process and analysis phases of inquiry. Here we shall focus on some special problems that behavioral science methods present in eliciting and protecting confidential information.

1. Techniques for the self-reporting of behavior. These techniques include a wide range of tests (e.g., achievement or performance measures) questionnaires and scales (e.g., items in a masculinity-femininity scale or personality test), and interviews, among others. The critical matter here is whether and how the technique is linked to unique identification. Where unique identification is possible, protection is especially critical, since self-reports of behavior have considerable evidentiary value, more so than might ordinarily be the case when they derive from an impartial inquiry such as research. Where self-reports of illegal or other damaging forms of behavior are elicited, the government is obligated to provide legal protection if it sponsors the inquiry. Parenthetically, we might note here that the government assumes certain obligations if it sponsors inquiry for eliciting confidential information, not the least of which is an obligation to provide legal protection for that which is confidential and potentially harmful.

2. Direct observation and recording of behavior. Again the evidentiary value of such information is considerable, particularly when it has unique identifiers such as in audio-visual recording. Both information obtained from direct observation and from direct recording (e.g., tape-recording or

video-tapes) require special protection and special obligations to insure its protection. The participant observer is an especially vulnerable technique since the participant observer acquires information by virtue of position that might otherwise be disclosed as confidence but at the same time has a special status in providing testimonial evidence--as observer and as scientific observer. Direct observation poses especially difficult problems where entire groups rather than individuals are under observation since they are especially vulnerable, as previously noted to the disclosure of information from a large number of potential sources.

3. Investigator intervention in social situations. When investigators intervene in situations and that intervention itself gives rise to confidential information that is shared by all persons in the group (as in guided-group interaction techniques of intervention), the investigation has a special burden: whatever legal protection is afforded an investigator may be inadequate to forestall disclosure of information, particularly since group processes of sharing information--rumor, gossip, e.g.,--have their own dynamic elements. The problem poses a special moral or ethical dilemma since in these circumstances the confidential information is created by the research intervention and others become party to it because of the nature of that intervention. Indeed, but for the intervention, other parties might not be privy to the information. By way of illustration, imagine an experiment using guided-group interaction techniques with a group made up of alcoholics; under both interventions from the investigator or his agent or other members of the group, confidential information is disclosed and necessarily shared by all. We shall not review in depth here the special problems that such group techniques pose but simply note that they have enormous power to induce

confidential information that persons would not otherwise disclose; at the same time such processes have a potential for doing harm to participants that cannot be predicted. Interventions that are particularly designed to elicit information as well as to produce a separate result--such as group therapeutic or interview techniques--require special examination because they are both a potential for harm and a potential for harmful disclosure.

4. Informant and relational techniques. A surprising number of behavioral science techniques are based on a model not only of self-reporting but of informant reporting. The subjects are asked to report on another directly, e.g., what did your mother do then? or to describe relationships that necessarily supply information on others indirectly, e.g., did your father and mother have a quarrel over that? We call special attention to the fact that any technique which elicits information on social relationships not only poses problems of eliciting informed consent as noted earlier, but special problems of protecting confidences that were not secured by informed consent. They pose special problems not only because consent was not obtained but they must qualify the extent to which anyone who supplies the information has a right to request its disclosure. The very nature of information about relationships when they become implicated in a research inquiry that developed it as an item of information is that it involves relationships between the parties to it and the investigator who structured it as "relational information". Thus questions like; "do you hate your mother?"; "was your father working at this time?"; "how much education does your mother have?" and many more intimate questions than these provide information on persons related to the participants being studied or on their relationships. Whenever such information is elicited, investigators have a special obligation

to protect that information from harming the other parties as well as the participant who gave informed consent from disclosure.

We note in passing that behavioral science research can provide complex problems of protection of informant information. Suppose, for example, one wished to study an informing process by investigating police use of informants in law enforcement, securing the confidence of both the police and their informants. Without legal protection for confidentiality the study would be impossible, yet it must rank as a rather high priority in understanding an important problem in the study of police practices and their effect on institutions of privacy.

5. Sociometric techniques. Sociometric techniques, as noted earlier, pose special problems in securing informed consent; they also pose problems of special protection since disclosure of information on any person in the network is potentially harmful to all others. Thus studies of delinquent gangs, gay bars, a military squadron, and similar phenomena pose problems of special protection of confidence.

6. A case history of technique. Any study employing a case history technique that requires the retention of information that is uniquely identifiable over a long period of data collection and analysis must be specially protected since it is more vulnerable to both unauthorized and compulsory disclosure. The use of techniques that preclude the complete and early destruction of identifying information require both that special precautions be taken to protect the processing and storage of information and that special forms of legal protection be available if disclosure of the information is potentially harmful.

The Need for Formal Punitive Sanctions as Protection. The more biomedical

and behavioral science inquiry is organized to include investigators and employees, each of whom undertakes one or more specialized tasks, the more administrative control that must be exercised and the less likely professional ethics, commitment, and self-regulation can be counted upon to protect confidentiality. Not only must greater precaution be taken to protect the confidentiality of information from those outside the research organization who might seek access to it but its unauthorized or illegal use by employees. A typical survey research study, for example, might involve more than a hundred different employees who could have access to confidential information. Others may also have access to it who are not employees, such as student trainees and assistants who volunteer their services in exchange for training.

The more potentially harmful the disclosure of confidential information, the greater the obligation for its protection. Where serious harm could result from its disclosure, investigators or sponsors must have access to formal sanctions for any unauthorized disclosure or misuse. The proposed LEAA regulations for the protection of confidentiality of identifiable research and statistical information make provision for sanctions. Section 22.29 provides (28 CFR):

"Where LEAA believes that a violation has occurred of Section 524a, these regulations, or any grant or contract conditions entered into thereunder, it may initiate administrative actions leading to the termination of a grant or contract, commence appropriate personnel and/or other procedures in cases involving Federal employees, and/or undertake appropriate legal actions leading to imposition of a fine not to exceed \$10,000 against any person responsible for violation."

Any employee of any investigator hence is subject to a fine of \$10,000 if he/she in any way knowingly violates the protections provided for confidentiality of identifiable research and statistical information. Should

investigators seek to safeguard confidentiality of identifiable information where persons who are not ordinarily employees might be given access to it, such protection is easily afforded by nominal appointment (\$ a year appointment, for example) as an employee.

IV. MINIMIZING RISK FROM DISCLOSURE OF CONFIDENTIAL MATTERS

The main risk of harm in much behavioral science inquiry stems from the disclosure of private matters to which socially harmful responses are then made. We have pointed out that even the mere refusal to grant informed consent and its documentation can pose risks to participants when that simple fact is disclosed. For many kinds of inquiry, moreover, uniquely identifiable information results from the procedures required to accession subjects--they ordinarily are not volunteers--and from the procedures for acquiring and processing information. Such information should be protected insofar as possible not only if there is risk of harm but if the participants desire its protection for any reason whatsoever. Finally, we noted that investigators often become privy to private matters that are not intended by the mode of accessioning participants or by eliciting procedures; acquiring information often is an unintended consequence of the necessity for gathering data in social situations that have a dynamic life of their own. The disclosure of these unintended matters may also harm individual and corporate actors and the risk of their disclosure must be minimized if behavioral science inquiry is to continue as a vital form of scientific inquiry in the public interest--an interest that is minimally presumed whenever government sponsors research. We shall examine briefly some modes for minimizing risk from disclosure, focusing particularly, however, on forms of legal protection that government sponsors may provide for inquiry involving individual and corporate actors.

Protection by Anonymity in Accessioning Participants and Eliciting Information. There are many different techniques for accessioning participants and eliciting information that minimize risk because they ipso facto insure anonymity. These have been discussed briefly in general terms. No specific

catalogue of them is presented here. We previously indicated that two rules might well apply when there is risk of harm from disclosure of information--provided that disclosure is not a matter of formal contract, as it may well be in much evaluation research. These rules may be stated:

1. Information that may cause harm if disclosed should not be collected unless it is necessary to the particular inquiry;
2. When the objectives of a particular inquiry will not be undermined by either accessioning participants anonymously or by anonymous procedures for eliciting information (or both), they should be required over any other procedure of accessioning or elicitation.

Yet, as we have noted, there are distinct limits to the use of such anonymous procedures. Among those we have mentioned are these: (1) identifying information is necessary to increase the validity and reliability of information and to estimate error in information; (2) identifying information is necessary for many designs that measure changes in the behavior of individual or corporate actors; (3) identifying information, and even its disclosure, may be necessary in evaluation research; (4) identifying information is necessary to some eliciting and data gathering procedures that are essential to a particular form of inquiry; and (5) identifying information is necessary when information from independently derived sources must be collated, e.g., information derived from interviews and records of past behavior are brought together for the same individual or corporate actor. The list is not exhaustive but uniquely identified. Several rules may be stated with respect to safeguarding uniquely identified information from disclosure:

1. Unique identifiers should not be collected unless they can be demonstrated to be essential to the particular inquiry.

2. Similarly, identifiers that, when taken collectively, provide unique identification should not be collected unless they are essential to a particular inquiry.
3. Any identifiers should be separated from any information sources as soon as they no longer are essential to an inquiry; identifiers should then be destroyed unless it is demonstrated that they are necessary to some later stage of inquiry.
4. All information on identifiers that may be linked to information and all information that has a potential for unique identification should be physically protected from access by anyone other than authorized personnel. Institutional sponsors and principal investigators should be legally obligated to provide such physical protection when there is risk of harm from disclosure. (28 CFR 22.23; (5); 42 CFR 2a4;(C)).
5. Access to uniquely identifiable data "shall be limited to those employees having a need therefore, and that such persons shall be advised of, and agree to comply with these regulations" (28 CFR 22.23: (2)).
6. Provision shall be made for the final disposition of any identifiable materials either by their complete destruction upon completion of a research inquiry or by separation and destruction of any identifiers or by provision for maintaining their security to make possible longitudinal or continuing studies (28 CFR 22.25). Special attention is called to the fact that unique identifiers pose special problems for retention, particularly when each bit of information has unique identification as it does in tape or video-tape recordings. More

stringent criteria for protection retention must apply to the retention of unique identifiers. Attention is called also to the fact that government sponsors have responsibilities under the Freedom of Information Act to notify and make accessible records that are uniquely identifiable, including research records they may acquire from sponsored research. Any transfer of records with uniquely identifiable information to a government sponsor thus poses enormous administrative burdens of notification, problems of correcting a record, etc.

Legal Protection for Compulsory Disclosure.

The growth of behavioral science inquiry has brought with it the recognition that the information acquired has uses for other than scientific inquiry. Information gathered by behavioral scientists like that gathered by journalists often is useful to others as well. Law enforcement agents, legislative, executive, and judicial bodies often find useful information that is uniquely identifiable and may seek to compel its disclosure to accomplish their own ends. It goes, almost without saying, that the ends of such bodies at times not only conflict with those of behavioral science inquiry but taken collectively they threaten the very foundations of that inquiry by the ways in which information is used.

The need to protect information gathered in behavioral science inquiry from use by others is considerable. As Nejelski and Peyser (1975:B-1) note, research participants have "a paramount interest in keeping the invasion of their privacy to a minimum and making sure that the information will not be the basis for prosecution or reprisal." Moreover, investigators have an interest in maintaining that privacy to insure the continuing participation of participants and to insure the quality of the information they acquire.

Sponsors of research have a similar interest. When the State is the sponsor, there may be conflicting interests--to protect the integrity of the scientific inquiry by protecting confidentiality but also to compel its disclosure for its other ends. Yet in the broad rather than in the narrow public interest, The State as Society would seem to have an overriding interest in protecting behavioral science inquiry from compulsory disclosure both in its general role of protecting free scientific inquiry and in its more special one as sponsor of specific research investigations.

There are two major forms of legal protection proposed to protect behavioral science inquiry from compulsory disclosure. The first form, that of a statutory privilege, protects from compulsory processes all information gathered in the course of an individual's research. These statutes are commonly referred to as "shield laws". They are designed to meet the needs of the State in terms of its general interest in protecting all behavioral science inquiry from compulsory processes of disclosure. The second form, that of a confidentiality certificate, protects from compulsory processes all individually identifiable information that is gathered in a particular research study sponsored and funded by the federal agency issuing the certificate. This form of protection meets the needs of a particular research sponsor and leaves unprotected any investigation where the government is not directly implicated as sponsor. It is obvious that a statutory privilege, since it offers general protection, has more far-reaching implications for the development of behavioral science than does the confidentiality certificate. Each is now considered in somewhat greater detail.

Statutory Protection.

There are at the present time few federal and state statutes that are

specifically designed to protect research investigators or research information and activity. A recent review of these statutes (Nejelski and Peyser, 1975: B-20-21) concludes that these statutes provide protection for only a small minority of all behavioral science investigators and investigations. They conclude, moreover, that there are major drawbacks to the limited and specific protection offered by current statutes, including those that provide a limited privilege for a given kind of research, such as drug research. Apart from the fact that they afford protection for only a small segment of the community in need of protection of confidentiality, some depend upon the discretion of officials for extension of the protection. As Nejelski and Peyser observe (1975:B-21): "Such discretion, as well as the requirement that researchers be "licensed" before they receive protection, could severely threaten the freedom of researchers to pursue controversial avenues of inquiry". The point is that the general interest of society in free scientific inquiry is much less well protected by statutes granting privilege for a specific inquiry than by one that extends it to all qualified investigators and their research activity.

We do not propose to discuss here in any detail proposals for a behavioral science investigators shield law. An example is provided in the model statute proposed by Nejelski and Peyser (1975:B-9-11). Rather, we shall examine some of the issues that are raised by statutory protection and the resolution of these Nejelski and Peyser provide in a model shield law for behavioral science investigators, together with some of the reasons pertaining thereto. With them, we define the major issues to be those of who is to be covered by the statutory privilege, to what matters shall the privilege extend, what is the scope of the protection, including possible limitations,

who may invoke the privilege, and right of waiver.

Who is to be Covered? Nejelski and Peyser (1975:B-31-32) observe that there are four principal ways of defining who is to be covered. The first is to simply name a category such as behavioral scientists, leaving undefined who is a behavioral scientist. Such an approach involves serious ambiguity that must need be settled by litigation. A second approach is to extend the privilege to certain kinds of information, such as particular kinds of records. This is the least ambiguous of all definitions of coverage but unfortunately leaves many kinds of legitimate inquiry without protection. One might add that statutes that grant discretion to officials to decide what is to be covered by limiting it to a specific inquiry have a similar limitation. The third major way is to specify a relationship between the person protected and a specific type of research activity, such as might be the case in granting protection to all persons who are engaged in research on the use and effect of drugs (be it noted as is the case now with federal legislation limiting that privilege to investigations under federal sponsorship). The advantage of this approach will depend upon the extent to which it can effectively cover a sufficiently large number of categories of research so as not to unduly restrict inquiry. The fourth approach is what Nejelski and Peyser identify as the functional approach and the one they use for their model statute. The functional approach confers protection on all individuals who perform a particular role in a specified way. This approach, they note, has the advantage of covering all individuals in all fields of inquiry including biological and natural as well as behavioral sciences if their activities conform to a specified pattern of behavior. Moreover, a functional approach extends the protection to all individuals involved in

the research process, not simply to those who actually elicit information from individuals. I note parenthetically that a limited functional approach is followed in some of the proposed federal regulations for confidentiality certificates, the alternative approach discussed later.

In considering the matter of what role is to be covered in what specified way, a number of issues arise. The problem of who is a behavioral scientist investigator is an especially difficult one since any mode of resolution by statute has limitations. Licensing poses problems of creating licensing authorities who may serve as gatekeepers. To require particular affiliations has similar limitations. To resolve the matter, Nejelski and Peyser propose to sacrifice specificity and precision "...to accommodate all those who have a bona fide involvement with research activity". They extend coverage to all individuals who in some way deal with information "obtained employing principles recognized or standards accepted in the field of inquiry" (1975:B-33).

A statutory protection must conform, of course, to the requirement that the research activity have a public benefit, to square the statute, as Nejelski and Peyser note, (1975:B-34) with the First Amendment.

To What Matters Shall the Privilege Extend? A general statutory privilege protecting research investigators from compelled disclosure of information would exempt investigators from their civic obligation to provide evidence in civil and criminal proceedings only when the information sought was obtained from research activity. The statute should restrict coverage "to information handled 'in the course of' research activity" (Nejelski and Peyser, 1975:B-35) to make certain that investigators are not covered for material obtained in their other roles. There will, of course, be grey areas in the

use of some behavioral science techniques with this provision, such as in participant observation where the research investigator has difficulty determining when research activity begins and ends as, for example, when a participant observer lives in a community to investigate compliance and conformity in it.

Any general statute should extend protection from compelled disclosure to all information that is obtained in the course of the research inquiry whether or not it is specifically covered by the research design and whether or not it is a matter of implicit or explicit promise in securing informed consent by promising confidentiality. This is a critical provision in all forms of protection from compelled disclosure. An example may show how broadly this provision might apply and why it is essential. Suppose one is doing a sample survey of people's attitudes toward child abuse and has consent to enter a private place to conduct the interview and the informed consent of the participant to interview about these attitudes. Now suppose that during the course of the interview the respondent punishes the child in such a way that it might well constitute child abuse. Let us further suppose that in a judicial proceeding information is sought from the interviewer on that incident of "child abuse". Should it be exempt from compelled disclosure? Our answer is that it should be for a number of reasons shared also by Nejelski and Peyser (1975;B-35-36).

First, any participant's interest in keeping the invasion of their privacy to a minimum and in insuring that any information they provide either orally or otherwise will not open them to prosecution or other possible harm from disclosure can be fostered only when the protection of the statute does not rest in a promise of confidentiality.

Second, while serious ethical issues can be raised in particular instances about granting such protection, the protection of any person should not depend upon the fortuitous circumstance of whether or not the investigator explicitly promised confidentiality for given information. As we have had occasion to note previously, any extension of confidentiality often is regarded by participants as a trust relationship--they come to have confidence in the interviewer as the relationship proceeds and even any explicit statements of exemption made in securing informed consent may come to be "forgotten" as trust develops. Such risks are generally less where the relationship is of short duration as with some research techniques, but as in others, e.g., prolonged observation or treatment, the trust relationship may become considerable. It is difficult for research investigators and participants to avoid those elements of trust and participants should not be placed in jeopardy because they either disclose or behave in ways that provide information that is potentially harmful to them.

Third, there are a number of modes of inquiry that often preclude explicit or implicit promises of confidentiality because of what they are measuring, as we have noted before in tests of personality or of qualities such as prejudice and discrimination, as will occur in direct observation of human behavior, and as in the study of social relationships. One cannot, as noted before, study social relationships without becoming privy to information about others whose consent was not obtained and who deserve the protection of confidentiality. A wife who talks about her relationship with her husband is not the only party subject to protection; her husband is as well if that information is also potentially harmful to him.

Finally, it should be noted that if any statute were to be open to

considerable litigation as might well be the case when what is at stake was what is and what is not covered by the privilege, it will lose its protection and the benefits to scientific research that it is designed to provide. We would maintain that an exclusion from protection of all information that was not a specific matter of consent will open the protection to just such damage.

We shall simply note here that matters we have previously discussed must also be covered by any viable shield law: (1) the identity of the subject, whether by unique identifiers or other means of unique identification, including the specific knowledge that they were approached and refused informed consent since that may be damaging; (2) the contents of all communications with any participant, any information acquired through direct or indirect modes of observation, and the work product of investigators. The reasons for being sure these are protected have already been provided.

What Shall be the Scope of the Protection and any Limitations? There are a number of reasons, as Nejelski and Peyser note (1975:B41-42), why it is not quite appropriate to regard a research investigator privilege as either absolute or qualified. Those matters aside, ideally one wants to provide the maximum possible protection, given the ever present problem that the "law is what the courts decide". The question of maximum possible protection perhaps is best approached by answering the question of the circumstances under which the privilege will be divested while seeking the maximum possible coverage.

There are many types of proceedings to which the privilege might apply, including legislative, executive and judicial proceedings. They include investigative and adjudicatory proceedings. While it can be maintained that

investigative proceedings are potentially more damaging than adjudicatory proceedings and the privilege should extend only to the former, particularly if the identity of the participant or source of information is specifically excluded in adjudicatory proceedings--in short, that a qualified privilege extend to the contents of communication. There is considerable risk in trying to maintain that distinction and a simple example may show why. Were one to report that all of the participants in a given inquiry were, say, drug users and were it known from some independent source that a given person was a participant in the study, identity remains unprotected. Even more qualified statements about subgroups can similarly lead to disclosure. I note, parenthetically, that investigators have an obligation to protect identity in the manner they report research results and that if statements are made of the sort above, they risk exposure of identity.

Quite clearly, all compulsory proceedings, whether legislative, executive, or judicial, should be covered if maximum protection is desired. The language of the proposed protection of identity in human subject research of DHEW might well apply to a general statutory privilege: "Persons...authorized may not, at any time, be compelled in a Federal, State or local civil, criminal, administrative, legislative, or other proceeding to identify the research subjects encompassed by the Certificate, except in those circumstances specified..." (matters of waiver) (42 CFR2a7;(a)). Note that the scope extends here to all levels of jurisdiction, a matter that clearly requires separate legislative authority.

The matter of whether there should be further qualification dependent upon other overriding interests is also at stake in a statutory privilege whether general or specific. Among the major overriding interests often

considered are those of national security, law enforcement, prior crimes and future crimes. We shall not review the arguments for and against their inclusion or exclusion. The reader is referred to Nejelski and Peyser for arguments against qualification for information relating to national security, law enforcement, and prior crimes, arguments that appear to this research investigator as compelling. There is agreement, however, that information on further crimes should be subject to compulsory disclosure, particularly for the more serious or heinous crimes.

There are, finally, some issues of a statutory privilege for research investigatory interests conflicting with constitutional interests and other federal or state statutes. These matters would require an extended discussion, some of which is given by Nejelski and Peyser (1975:B-48-55). We would make note here only of the real possibility that a criminal defendant should not be violated by any statutory privilege. There is some risk that if the contents of communications as well as specific identity of sources are excluded by statute it violates a defendant's Sixth Amendment interest--the right of the accused in criminal prosecutions to have compulsory processes for obtaining witnesses in his favor. The researcher privilege previously mentioned covering the content of communications in criminal prosecutions is therefore potentially in conflict with the Sixth Amendment rights of persons. Because the research investigator's privilege status rests in the First Amendment interest in providing the public with information, the statute provides the possibility of conflict between two constitutionally protected interests. A defense subpoena permitting the defense an exception "...operative only if the defendant is acting in good faith in requesting the contents of communications or observations of the researcher" (Nejelski and Peyser, 1975:B-49) may therefore be necessary in balancing First and Sixth Amendment

rights. There should, however, be no exception to the provision that the identity of all research participants be protected and if, therefore, the effect of disclosure of contents is to disclose the identity of participants, the protection of identity of subjects should be overriding.

We make simple note in passing that both the Federal Reports Act and the Freedom of Information Act are federal acts that would need to be accommodated to the kind of proposed federal statute as described in any federal statute.

Who May Invoke the Privilege? A central issue in invoking the privilege is who assumes the burden of proof for qualification. It can be placed either upon the person asserting the privilege or upon the party requesting the information. Placing the burden of proof on the person asserting the privilege would require some form of proof that the information sought is research data as defined by the statute while placing it upon the party requesting the information requires proof that what is sought are not research data. Any failure by the requesting party to sustain this burden means the privilege is automatically effective. There are a number of reasons why the burden should perhaps fall upon the party asserting the privilege, the most compelling being that if the privilege confers the broad coverage deemed necessary for effective protection, it should be relatively easy for investigator's to invoke the privilege and the burden should therefore fall upon the investigator.

Nejelski and Peyser (1975:B-56) also note that the research investigator's privilege can be further strengthened if the situations in which a subpoena can be issued are carefully circumscribed by statute.

Who May Waiver Privilege, When and How? The proposed statute is designed to provide maximum possible protection against compulsory processes of

disclosure of the identity of participants in research and any information connected with research activity. The question arises, however, whether there should be any power to divest the privilege by voluntarily disclosing privileged information. On the face of it, there is compelling argument that the person who provided the information should have the right to divest the privilege. Yet the matter of divestiture is more complex, particularly when it is kept in mind that the power to waive any privilege is to provide substantial control over its exercise. Whenever information is provided, however, both participants and investigators acquire some right in the information and its disclosure. While the research participant clearly has the greater stake in the information, that of the investigator is not insubstantial. The investigator has obligations to protect information that pertains, at the same time, to others as well as to the participant and to protect the integrity of the specific inquiry which might well be damaged were disclosure to take place, e.g., while the investigation is still in progress.

One way of balancing these rights is to require that both the participant and the investigator must voluntarily divest themselves of privilege, a resolution opted for by Nejedlski and Peyser (1975:B-60). There could be some qualification on the investigator's right, however, by providing that he has the right to withhold consent only on proper showing of its potential damage to the investigator or others if disclosed.

Lest considerable damage be done to the statutory privilege on compulsory disclosure by an absolute right of the research participant to voluntary waiver, provision should be made to limit waiver to only certain situations. The one obvious condition is to when waiver should apply is that when the party or parties who are empowered to waive the privilege can do so only in

response to a subpoena or other legal process. Any other disclosure of the information, whether by the parties to the research activity or by others, should not dissolve the privilege. Unless specifically exempted, then, government agencies, for example, would not have access to specifically identifiable information or the identity of participants, including access for audit or as a research sponsor. The role of the government in these latter respects is not unimportant, and, as we shall later note, those powers are reserved in granting a confidentiality certificate.

Earlier we noted that the presence of third parties makes it difficult to protect confidentiality, since they are always potentially a source of disclosure of confidential information. Yet inevitably in some behavioral science inquiry there are third parties present. Their presence, however, should not divest the privilege of confidentiality, however, as Nejelski and Peyser conclude (1975:3-60-61): "Logically, the presence of a disinterested third party would destroy confidentiality at the outset." But, "The researcher's privilege as provided in the proposed statute...is not based on confidentiality. In addition, the professional privileges protect only information revealed in the course of a direct conversation between the professional and client. The researcher's privilege protects information obtained by the researcher employing techniques that involve methods other than direct communication...If the privilege were automatically waived when a third disinterested party was present, the protection given in the mentioned situations would be meaningless."

These, then, cover the main elements and reasons for them in a general statutory privilege protecting research investigators and their participants. There are good reasons to maintain that such protection should be afforded

all inquiry where human life is involved, whether as individuals or collectively. Yet there are both practical and other reasons why this course might not be taken. Practically, such protection requires considerable legislative activity by the Federal government and the States. There will be far from uniformity in the enacted statutes adopted by states and such protection might be long in coming. While it might be commended as a long-run strategy for protection since it provides protection for all legitimate scientific inquiry on human beings and their social life, in the meantime there also is a need for protection. The role of government in fostering the right of the public to information, moreover, is clear and unmistakable when it is the research sponsor. We turn, therefore, to the ways that the federal government may protect confidentiality in its role as research sponsor, dealing specifically with protection through the discretionary granting of confidentiality certificates. Before doing so, we simply note that the federal government can do so in other ways. It may, for example, provide protection for a given kind of research categorically specified at law. This is done, for example, at the present time, for some research on drug use. Some protection also is provided if the government chooses to interplead in a given proceeding, and so on. We shall focus on the confidentiality certificate, however, because of its special status in proposed federal regulations by DHEW (42CFR2a) and LEAA (28CFR22) and note particularly that the LEAA proposed regulations have some advantages for investigators and participants not now included in the proposed DHEW regulations.

Confidentiality Certificates. The LEAA proposed regulations refer to a Privacy Certificate while those of DHEW refer to a Confidentiality Certificate. The purpose of these certificates is "to protect the privacy of individuals by requiring that information identifiable to a private person obtained in a research or statistical program funded by LEAA may only be used and/or revealed for the purpose for which it was obtained" (28 CFR 22.2) and "The proposed amendment sets forth procedures under which persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, may apply for an authorization under section 303 (a) of the Public Health Service Act (42 U.S.C. 242a (a)) as amended by Pub. L. 93-282, to protect the privacy of the research subjects by withholding from all persons not connected with the conduct of the research the names and other identifying characteristics of such research subjects." (42 CFR 2a). The certificate, in both cases, is granted to the institutional sponsor for a proposed study by a designated principal investigator(s). We make note of the fact that the LEAA protection has somewhat less scope than that of DHEW, since LEAA extends the protection to "information identifiable to a private person" where a private person includes "any individual, partnership, corporation, association, public or private organization . . . or combination thereof . . . other than an agency, or department, of Federal, State, or local government, or any component or combination, thereof" (28 CFR 22.2 (a), (b)) making it inapplicable to government agencies while DHEW includes them: "Person means any individual, corporation, government, or governmental subdivision or agency, business trust partnership, association, or other legal entity" (42 CFR 2a.2(b)).

We note in passing that statutory authority, of course, is essential

to make the issuance of a confidentiality certificate possible. Such statutory authority is now provided by the Congress for only a limited number of federal agencies for their behavioral science research.

Degree of Protection Afforded. In describing the protection afforded the introduction to the DHEW regulations note (Federal Register 40:234:56693):

The proposed regulations provide that persons receiving an authorization of confidentiality may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify the research subjects encompassed by the authorization (2a.7(a)), but that such persons are not authorized to refuse to reveal identifying information where (1) the subject (or, if legally incompetent his guardian) consents, in writing, to the disclosure of identifying information, (2) the medical welfare of the subject would be threatened by a failure to reveal such information, or (3) release of such information is required by the Federal Food, Drug, and Cosmetic Act or the regulations promulgated thereunder (2a.7(b)). The purpose of these exceptions is to prevent the protection against compulsory disclosure of identifying information from being invoked to the detriment of the research subject.

The regulations also set forth procedures on termination of Confidentiality Certificates. The protection afforded by a confidentiality certificate is, however, permanent with respect to subjects who participated in research during any time the authorization was in effect.

In the proposed DHEW regulations research means " . . . any activity that is intended and designed to establish, discover, develop, elucidate, demonstrate, or confirm information or procedures. The term includes, but is not limited to, behavioral science studies, surveys, evaluations, and clinical investigations " (42 CFR 2a.1(c)). Clearly this is a sufficiently broad definition to encompass what we have previously addressed as behavioral science inquiry. Yet, it must also be clear, that the discretionary authority to decide whether a particular inquiry qualifies is left to the Secretary or other persons to whom that authority is legitimately delegated. LEAA may have a somewhat broader definition, providing that "Research or Statistical

information--means any information which is collected during the conduct of a research or statistical project or derived from such information, and which is intended to be utilized for research or statistical purposes. The term includes information which is collected directly from the individual or obtained from any agency or individual having possession, knowledge, or control thereof" (28 CFR22). Despite this somewhat broader definition, the published proposed LEAA regulations specifically excluded from research " . . . information which is unrelated to project research and statistical objectives" (28 CFR 22.23(4) & 22.27(4)). However at recent hearings on the proposed regulations there was apparent agreement to eliminate this latter restriction for reasons already discussed in our protection of confidentiality section. DHEW is silent on the matter so that much would depend upon how the research clause is construed.

Both DHEW and LEAA provide explicit protection relating to "identifying characteristics." The DHEW regulations may have a somewhat more limited protection as identifying characteristics as " . . . refers to any data collected on an individual by a researcher that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual which could reasonably distinguish that individual from all others in the study, including but not limited to fingerprints, voiceprints, or photographs" (42 CFR 2a2:(g)); though the definition of person as already noted includes all individual and corporate actors. LEAA makes explicit that "information identifiable to a private person--means information which either (1) is labelled by name or other identification, or (2) can by virtue of sample size or other factors, be reasonably interpreted as referring to a particular private person" (28 CFR 22.2:(e)), though as noted, the definition of a private person specifically excludes government.

Regardless of which is more limited in what respects, the definition of private person in proposed DHEW regulations and of identifying characteristics in LEAA proposed regulations may afford the maximum possible protection.

The question of who is to be afforded protection and how to be eligible for a certificate likewise differs among proposed regulations. DHEW stipulates that any person engaged in the applicable research described above ". . . who desires authorization to withhold the names, and other identifying characteristics of individuals who are the subject of such research from any person or authority not connected with the conduct of such research may apply to the Office of the Director of the National Institute on Drug Abuse . . . , National Institute of Mental Health, or . . . National Institute on Alcohol Abuse and Alcoholism . . . for an authorization of confidentiality. Such an application may accompany the submission of an application for grant or contract assistance" (42 CFR 2a3:(a)). The proposed regulations thus applies only to some DHEW sponsored research. The LEAA proposed regulations stipulate that "Each applicant for LEAA support either directly or under a State plan shall submit, as a condition of approval of any grant application or contract proposal, a Privacy Certificate" (28 CFR 22.23:(a)). Since a considerable range of kinds of research can be sponsored by LEAA and none is excluded, there are no restrictions by specific kind of research sponsored by the agency--though it might be argued that all DHEW sponsored research would be comparable to all Department of Justice sponsored research. In any case, so far as the issues confronting the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research are concerned, it should be apparent that only the behavioral science research under the above sponsors could be protected by a Confidentiality Certificate.

All such research should be protected where confidentiality and its protection is at stake.

Requirements for Certification. We shall not review in detail the specific requirements that institutional sponsors and investigators must meet to be eligible for a Certificate of Confidentiality in both proposed DHEW and LEAA regulations. We shall simply make note of some, since these requirements are discussed in many sections of this paper, while reserving comments for others. The following are the major requirements (DHEW 42 CFR 2a4):

1. The Secretary may require any pertinent information other than that specified below;
2. "The name and address of the individual primarily responsible for the conduct of the research and the sponsor or institution with which he is affiliate, if any;
3. "The location of the research project and a description of the facilities available for conducting the research, including the name and address of any hospital, institution, or clinical laboratory facility to be utilized in connection with the research";

We note that for much behavioral science inquiry while the location of the project can be specified in the application, the specific location of sites where procedures will be performed is not generally available. The most one may be able to specify is the kind of site, e.g., a stratified probability sample of U. S. households.

4. "The names, addresses, and summaries of the scientific or other appropriate training and experience of all personnel having major responsibilities in the research project";

We would only make note of the fact that some of these persons may be known only after funding and employment so that provision should be made to supply them at some later point, if that is deemed essential; otherwise a statement of their qualifications when employed should suffice.

5. "(i) An outline of the research protocol for the project including, where applicable, the following information: (ii) A statement of

the methodology to be followed including: (A) The number and types of subjects (e.g., age, sex, education) who will be used in the research project; (B) The type of information which is to be collected and the instruments and methods for such collection; and (C) The procedures for safeguarding of data on the research subjects, which shall include as a minimum an assurance that records containing any information pertaining to a research subject shall be kept in a locked file cabinet, safe, or other similar container when not in use; and (iii) A statement: (A) From applicants who receive DHEW grant or contract support for the research project with respect to which a Confidentiality Certificate is requested assuring that they will comply with all the requirements of 45 CFR Part 46, "Protection of Human Subjects," or

(B) From all other applicants assuring that they will, if it is determined by the Secretary, on the basis of information submitted by the applicant, that (1) the subjects will be placed at risk and (2) a decision to allow the subjects to accept the risks is warranted, comply with the informed consent requirements of 45 CFR 46.3(c) and document legally effective informed consent in a manner consistent with the principles stated in 45 CFR 46.10. If a modification of paragraphs (a) or (b) of 45 CFR 46.10 is to be used, as permitted under paragraph (c) of this section, the applicant will describe the proposed modification and submit it for approval by the Secretary.

(5) The estimated date for completion of the project;

(6) A specific request for authority to withhold the names and other identifying characteristics of the research subjects and the reasons supporting such request;

(7) An assurance that if an authorization of confidentiality is given it will not be represented as a general endorsement of the research project by the Secretary or used to coerce individuals to participate in the research project; and

(8) An assurance that the research subjects will be immediately advised of any termination of the authorization of confidentiality. (See 2a.8(c)).

We make specific note of only two provisions here that may raise some questions.

Requirement 8 states that one must grant assurance that "an authorization of confidentiality . . . will not be represented as a general endorsement of the research project by the Secretary or used to coerce individuals to participate in the research project." The requirement seems a reasonable one, only if certain matters are explicit. To effectively represent to potential participants that one can afford the protection provided by the confidentiality certificate one must be able to make representations that such protection is afforded by Federal regulations and on request furnish

proof that such a Certificate of Confidentiality has been issued. Indeed when matters of potential harm from disclosure of confidential information are at stake, one may have an affirmative obligation to provide a copy of the certificate to all potential participants to fully inform them of the nature of that protection so that one meets the requirement of an "informed consent." That in doing so, one risks the possibility, even the likelihood, that some participants will on having that information change their minds and become participants should not be interpreted as "coercive" of participation. A "reasonable and informed man" might well change his/her mind when provided with a copy of the Confidentiality Certificate.

Since the LEAA Privacy Certificate is applied for in connection with a regular research application, no special provisions of the foregoing are stipulated. It is assumed that the obligation to provide them in DHEW sponsored research, including the requisite assurances, must be made when they occur in conjunction with a regular application, an option that is provided.

The Certificate of Confidentiality or Privacy Certificate and Its Limits

The proposed DHEW regulations provide some general guidelines for the Secretary to take into account in issuing a Confidentiality Certificate (42 CFR 2a6) while they are only implied in the statement of purpose for the Privacy Certificate in LEAA proposed regulations (28 CFR 22.1).

The discretion of the Secretary is constrained to take into account:

- (1) The soundness of the purposes and methods of the research project;
 - (2) The scientific or other appropriate training and experience of all personnel having major responsibilities in the research project;
 - (3) The suitability for use in the research project of the proposed subject population and the protections to be afforded to subjects; and
 - (4) Such other factors as he may consider necessary and appropriate.
- All applications for confidentiality certificates shall be evaluated by the Secretary through such officers and employees of the Department

and such experts or consultants engaged for this purpose as he determines to be appropriate.

(b) After consideration and evaluation of an application for an authorization of confidentiality, the Secretary will either issue a Confidentiality Certificate or a letter denying a Confidentiality Certificate, which will set forth the reasons for such denial, or will request additional information from the applicant.

The LEAA implied guidelines refer to matters of protecting privacy and clarifying the purposes for which identifiable information may be used or revealed. It likewise seems apparent that the requirements for information on application are addressed to the major criteria governing privacy certification.

Elements in the Confidentiality Certificate. The proposed DHEW regulations stipulate the elements in the Confidentiality Certificate and major limitations on its protection and use (42 CFR 2a.6(b), (c), (d)).

The Confidentiality Certificate will include:

- (1) The applicant's name and address;
- (2) The name and address of the individual primarily responsible for conducting the research, if such individual is not the applicant;
- (3) The location of the research project;
- (4) A brief description of the research project;
- (5) The Drug Enforcement Administration registration number for the project, if any; and

(6) The date of expiration of the Confidentiality Certificate.

(c) A Confidentiality Certificate is not transferable and is effective only with respect to the names and other identifying characteristics of those individuals who are the subjects of the single research project specified in the Confidentiality Certificate. The recipient of a Confidentiality Certificate shall, within 15 days of any completion or discontinuance of the research project which occurs prior to the expiration date set forth in the Certificate, provide written notification to the Secretary. If the recipient determines that the research project will not be completed by the expiration date set forth in the Confidentiality Certificate he may submit a written request for an extension of the expiration date which shall include a justification for such extension and a revised estimate of the date for completion of the project. Upon approval of such a request, the Secretary will issue an amended Confidentiality Certificate.

(d) The protection afforded by a Confidentiality Certificate does not extend to significant changes in the research project as it is described in the application for such Certificate (i.e., changes in the personnel having major responsibilities in the research project, or changes in the research protocol affecting the number and types of

research subjects or the nature of their participation in the project). The recipient of a Confidentiality Certificate shall notify the Secretary of any proposal for such a significant change by submitting an amended application for a Confidentiality Certificate in the same form and manner as an original application. On the basis of such application and other pertinent information the Secretary will either:

(1) Approve the amended application and issue an amended Confidentiality Certificate together with a Notice of Cancellation terminating the original Confidentiality Certificate in accordance with 2a.8; or

(2) Disapprove the amended application and notify the applicant in writing that adoption of the proposed significant changes will result in the issuance of a Notice of Cancellation terminating the original Confidentiality Certificate in accordance with 2a.8.

We note especially the provisions stating that "The Confidentiality Certificate does not extend to significant changes in the research project as it is described in the application for such Certificate" and that " . . . the recipient of a Confidentiality Certificate shall notify the Secretary of any proposal for such a significant change by submitting an amended application for a Confidentiality Certificate in the same form and manner as an original application." This provision to be sure appears quite reasonable on grounds of holding investigators accountable so that they do not extend the range of inquiry unduly to cover matters that invade the privacy of participants and that might not otherwise be approved by sponsors of the Confidentiality Certificate as well as to constrain against altering substantially risks of participants. Yet, given the relative lack of guidelines (provided only by a few examples) as to what constitute "significant changes," it can lead both to improper regulation of scientific inquiry and to burdensome administration and decision-making. Many behavioral science studies undergo a large number of small changes as they proceed; it is more likely to occur with some designs than others. Such small changes might be regarded by others to cumulate into a "significant change." Experimental designs are less likely to involve such modifications

than other designs. In general, the more systematic the design and procedures used, the fewer the modifications called for. But the more exploratory the inquiry, the less likely it is to utilize more systematic methods. Exploratory investigations and the less experimental methods might be burdened unnecessarily if no provision is made for approving modifications within limits that construe significant in a broad rather than a narrow sense. As it stands, the term "significant" is perhaps so ambiguous as to pose a questionable standard for regulation.

The power of the Secretary, moreover, to disapprove such proposed changes can pose problems of serious interference in scientific inquiry since there are virtually no guidelines in the proposed regulations to constrain his discretion. Moreover, the notification that any such changes will automatically entail the issuance of a Notice of Cancellation terminating the original Confidentiality Certificate could be tantamount to cancelling any further inquiry deemed appropriate by an investigator and approved by an Institutional Review Board. While it may be necessary to utilize such sanctions to effectively control project alterations by investigators, it would appear that unless constraints are imposed on how judgment is to be made regarding "significant changes in the research project," any investigator is open to arbitrary control of the research design.

Perhaps it would be more reasonable to leave changes in design to investigators and their institutional sponsors, setting guidelines that any changes not alter the basic objectives set forth in the original inquiry provided they do not increase the risks from harm that participants assume. The research sponsor might then be expected to approve the changes and they would be covered by the Confidentiality Certificate unless when the Secretary is notified of these changes, he is obliged to set forth specific reasons

why the proposed changes do not meet criteria for approval. This procedure would place the burden of proof upon the institutional sponsor and on the Secretary issuing the Confidentiality Certificate. Both should be obliged to set forth explicitly the reasons supporting any adverse decision before an amended application can be rejected for protection by a Confidentiality Certificate. When an Institutional Review Board rejects an investigator's modifications that are to be covered by a Confidentiality Certificate, the investigator should have a right to "appeal" that decision to the Secretary. Both the Institutional Review Board's explicit statement of reasons for rejection and the investigator's rejoinder should be forwarded in that case to the Secretary for a final decision. To do otherwise is to raise the spectre of unwarranted inference in scientific inquiry.

Protection Afforded with Waiver and Other Exceptions. The DHEW proposed regulations set forth the following provisions regarding the effect of a Confidentiality Certificate and exceptions to those effects (42 CFR 2a.7):

2a.7 Effect of Confidentiality Certificate: exceptions.

(a) Subject to the exceptions set forth in paragraph (b) of this section, a Confidentiality Certificate authorizes the withholding of the names and other identifying characteristics of individuals who participate as subjects in the research project specified in the Certificate while the Certificate is in effect. The authorization applies to all persons who, in the performance of their duties in connection with the research project, have access to information which would identify the subjects of the research. Persons so authorized may not, at any time, be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify the research subjects encompassed by the Certificate, except in those circumstances specified in paragraph (b) of this section.

(b) Exceptions. A Confidentiality Certificate granted under this part does not authorize any person to refuse to reveal information which would identify a research subject where (1) the subject (or if he is legally incompetent, his guardian) consents, in writing, to the disclosure of such information, (2) the medical welfare of the research subject would be threatened by a failure to reveal such information, or (3) release of such information is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or the regula-

tions promulgated thereunder (Title 21, Code of Federal Regulations).

The proposed DHEW regulations basically provide protection against compulsory disclosure of identifying information. As noted earlier this provision offers considerable protection to both participants and investigators. The limitation of the protection to identifying characteristics, which includes the data so identified, provides sufficient protection in a large proportion of behavioral science studies. Yet, as noted earlier, the power to compel disclosure of all other information, including the materials of investigators, could expose certain individual and corporate actors to harm simply because at times it is difficult to determine what is an identifying characteristic that might bring disclosure and what information others have that would make identification possible. It is well to bear in mind that the behavioral scientist is not the only one who may possess information with identifying characteristics; others may also have possession of some information. Where there is overlap in the two sets of information, each can become privy to the information of the other--a technique of expanding the amount of intelligence not unknown to intelligence and law enforcement agencies. Thus the simple removal of identifying characteristics does not guarantee that given some overlap in information by others, they cannot become privy to the confidential information the investigator seeks to protect. For that reason alone, one should be obligated to protect all the information at an individual level if there is any risk of harm on disclosure and, correlatively, that protection should be afforded against compulsory disclosure of all information. The appropriate standard then is that set forth in our discussion of shield laws--to protect all information that is gathered by research activity. Protection of all information related to a criterion of research activity provides greater

protection than does one based on a criterion of identifiable information.

The LEAA proposed regulations provide (28 CFR 22.28): "(a) Research or statistical information identifiable to an individual and/or copies thereof shall be immune from legal process and shall only be admitted as evidence or used for any purpose in any action, suit, or other judicial or administrative proceeding with consent of the individual providing such information, or, in any case in which information is obtained through means other than direct inquiry of the individual to whom the data pertains." Quite similar to the DHEW provision, it omits reference to legislative proceedings and while providing, as noted earlier, a somewhat broader definition of what is meant by "information identifiable to a private person," it still does not provide protection for other information connected in the course of research activity. Both regulations, as now proposed, offer no protection for information that is collected by inadvertence or as a consequence of natural occurrence in social situations to which investigators become privy, an omission we noted earlier that should be corrected in the interest of behavioral science inquiry.

The DHEW regulations make no provision for protection of the information against unauthorized or illegal use and sanctions therefore are not provided for in the case of misuse. Tort remedies are unlikely to be useful in aiding investigators to protect information from employee misuse or unauthorized access; special statutory and regulatory sanctions are required to provide investigators such effective control. Protection of this kind is provided for in the proposed LEAA regulations (28 CFR 22.29) where LEAA is authorized to take legal actions leading to imposition of a fine of not to exceed \$10,000 against any person who violates the provisions of confidentiality. The Commentary on the proposed regulations makes clear:

This would include the grantee organization, as well as particular individuals (including grantee employees) committing violations. (Federal Register 40, 186:44037)

The Commentary also makes clear that violations under transfer agreements are similarly covered by these sanctions.

The exceptions to the privilege accorded by the DHEW Confidentiality Certificate include both an individual's right to waiver and exceptions that seem applicable only to bio-medical research sponsored by the DHEW agencies covered by the proposed regulations. LEAA provides for the same waiver of privilege. The reader is referred to our earlier discussion of waiver of privilege for a consideration of qualifications on the participant power to waiver.

Apart from waiver of privilege, the question can be raised as to whether there are specific exceptions that should be provided for in any Confidentiality or Privacy Certificate. We previously discussed the obligation to disclose information on future crimes, at least those of a heinous nature. There are other matters that merit consideration as well:

1. Investigators should be permitted to transfer information identifiable to private persons to other persons or organizations for research or statistical purposes, provided they are covered by and legally bound by the same provisions governing confidentiality and the disclosure of information.

2. The Federal Government has a right and a duty to audit sponsored research. This probably means they must have access to information regarded as confidential to insure that at least research subjects were indeed subjects and were at least dealt with by certain procedures. The LEAA regulations provide for the sanction of government employees (28 CFR 22.29) if in any way they violate the provisions of section 524a of Pub. L. 93-83 Stat. 197,

the statutory authority for the regulations.

3. Provision is made in the LEAA regulations for staff access to confidential data (28 CFR 22.21:(b)), and they are similarly subject to federal employee sanctions as well as the specific sanction provisions of the regulations. Absent some guidelines governing when staff shall have access to confidential information, there is a risk that such monitoring might be used for other than the legitimate purposes of protection and audit. If the sponsor's interest lies in utilizing the information for research or statistical objectives, that should be made a matter of contractual agreement on the grant or contract award rather than as a blanket authority granted all staff in the regulations. If this form of protection from staff is not provided, other modes should be considered, e.g., that such information can be obtained only with the specific authorization of the Director and then only with a statement of the reasons why the information is requested. This latter provision should be a minimum requirement for any staff access to the confidential information in a research project.

Institutional Control. The procedures for approving research and applying for a Confidentiality Certificate in the proposed DHEW regulations fail to make clear what role the Institutional Review Board or institutional sponsor has with respect to approving or disapproving the request for a Confidentiality Certificate. LEAA provisions provide only for approval of the research by the institutional sponsor. The question of whether or not an investigator should apply for a Certificate of Confidentiality however is germane to the considerations of the Board. Yet a Board should never withhold approval from a research project because a Certificate of Confidentiality is requested while it may do so when it regards a Certificate of Confidentiality essential to protect subjects "at risk." The reasoning

behind this proposed guideline for Institutional Review Boards is that investigators should be permitted to request protection whenever they regard it as essential to their own as well as to participant protection. At the same time both investigators and Institutional Review Boards have a responsibility to protect the participants at risk and the IRB should have the power to require that one be requested if in their judgment it is essential for protection from harm.

V. SOME THOUGHTS ON THE REGULATION OF BEHAVIORAL SCIENCE INQUIRY

The Role of Government Sponsor.

To a growing degree, government has become the sponsor of biomedical and behavioral science inquiry. Support from both the private sector and from voluntary associations or foundations comprises an ever smaller part of the investment in research undertaken by employees of non-profit organizations. The obligations of government in regulating research and its responsibilities for harm done are far from clearly defined.

Current DHEW models of regulating biomedical and behavioral science inquiry on their face place the federal government in several protection roles: (1) those of protecting the government's general interest in the public's right to information and its particular interest in deriving specific benefits for its many functions (legislative, executive, and judicial) by setting program standards and objectives for research to qualify for funding; (2) that of protecting the rights of investigators from too much government interference by providing for institutional and peer review and making public the grounds on which applications are denied by the government agency; (3) that of protecting the rights of participants in research by establishing regulations requiring investigators to secure informed consent, protect subjects, etc. as a condition of their sponsorship. There are other ways that government research sponsors assume the legitimate mantle of protector, but the right to protect carries with it more than a responsibility to see that protection is adequate and in the public interest.

Some of that "something more" is the responsibility it perhaps might assume in its role as specific sponsor. The use of experiments, the growth

of evaluation research, and the creation of many other interventions combining research and social action objectives originate at least as often perhaps with the government sector than with the "voluntary" community of scientists. Many research proposals and some procedures are shaped to a substantial degree by government needs, government inducements, and government requirements. The government wants "cures" to physical, psychological and social ills and it shapes its programs and funding to do research on them-- a proper role, to be sure. Yet the more a government by its policies and programs provides inducements that shape what investigators do, the more it must pay attention to its responsibility for the consequences of research.

The more a government induces research that requires experiment, evaluation and action research, or other types of research that include interventions in social life, other than the interventions required by research procedures, per se, the more likely it is to do harm as well as good. This is so, if for no other reason than that even with a low probability of harm, the more of that kind of research, the more harm that is done by research. But since risks from some kinds of research are greater than others, the more the government induces investigators into high participant risk research, the more burden it should also assume for failures and liabilities. Such burdens should not fall exclusively on investigators and their institutional sponsors. If the government wants a cure to drug use and encourages research on drug use in human subjects, it has not only a strong obligation to protect those subjects, but it should incur some of the liabilities that may result from any harm done. Moreover, it should not readily do harm by disclosing confidential information or other means without overriding public interest. Matters of tort liability not altogether aside in

American law, government must increasingly recognize its responsibilities for the actions of its agents--directly or indirectly--as well as a need to protect participant and investigator interests. This may mean that all parties to government sponsored research, including the government as sponsor, must come to recognize there may be affirmative responsibilities as well as liabilities when harm is done--responsibility to help that may override liabilities that might otherwise obtain--and a responsibility to share in the costs from tort actions or other forms of settlement. It may not be enough to encourage protection by "informed consent", leaving the risks to fall to those who consent and the liabilities to those who are the immediate principal in securing it. To know risks and to consent is no protection that harm will not be done. Knowledge affects choice, but knowledge cannot insure that whatever risk is taken will not fall upon the chooser for it must fall upon some! How is such harm to be dealt with? Only by tort actions or the burden being borne by those who "freely chose" to consent? Perhaps that is not enough in a society where government encourages and accepts legal affirmative duties in matters of harm.

Individual and Corporate Actor Informed Consent.

Attention has been called to the strong likelihood that when research is undertaken that involves corporate actors, information often must be obtained not only on corporate behavior, per se, but from those who are members of the corporate actor (corporate actors include all forms of collectivities from families and other small groups to bureaucratic organizations). This necessity raises the problem that when the consent of the corporate actor (provided by some 'officially' recognized or legally authorized person) and of all members who must be involved in the research, each

has the power to control the actions of others and subvert the research goals by refusal to participate. There are two principal types of dilemmas in this respect. The first occurs when the corporate actor grants consent but its employees have a right to refuse consent to participate in their role as employee. This might occur, for example, when the federal government requires that a prison security program be evaluated but the guards refuse to grant their consent. We have suggested that this might be resolved by formal contract in making a grant that involves the corporate actor; the corporate actor then exercises an "employer right". Yet there might well be questions of limits to employer rights where research is involved and those matters must be explored.

A second dilemma occurs when employees grant their consent but the corporate actor refuses to do so for matters that involve the corporate actor. We noted that this could arise when, for example, teachers might grant their consent to investigate styles of school administration and their effects on learning, but the school administration would refuse to grant their consent. What is at issue here is the right of employees to disclose matters that involve the corporate actor. There likewise is not a simple answer to that question.

Both of the above dilemmas can occur for inquiry in private as well as well as public organizations. Consider, for example, the interest that LEAA might have in studying policing and security by both private and public organizations (it provides funding for both types of research). Studying policing in either the private or the public sector raises these dilemmas for requiring informed consent by all or only some parties of the corporate actor.

Without some reasonable balancing of rights to informed consent and rights to give and obtain certain kinds of information, much behavioral science inquiry on corporate actors becomes impossible. Need one add that in a modern complex society information on corporate actors may be of greater consequence than that sought on individuals apart from their roles for corporate actors?

Journalists, Behavioral Scientists and the First Amendment.

Both journalists and behavioral scientists seek to lay claim to First Amendment rights to protect their right to inquiry and to disclose information in the public interest. Both face serious difficulties in protecting their confidential sources of information by laying claim to a privilege from compelled disclosure of confidential information based on the First Amendment, though there is little argument that Congress "presumably has the power to fashion legislation such as a testimonial researcher's privilege to insure that the First Amendment rights of researchers are not infringed. Such legislation would apply both on the federal and state levels" (Nejelski and Peyser, 1975:B-28).

There are, however, substantial differences between them in their objectives, modes of acquiring information, and of dissemination of information. These must be kept in mind lest one assume their needs and requirements for protection are similar.

First, behavioral scientists always seek to protect any individual from any effect of public information while the journalist often seeks to do exactly the opposite. Generally, behavioral scientists seek to characterize aggregates, not individuals, and while journalists at times have a similar objective, often they do not. While both want to protect their sources of

information, their objective in doing so stems from quite different grounds. Journalists, not unlike some law enforcement agents, seek to protect the source of the information that is disclosed about some other individual or corporate actor. Their object may well be to do harm by disclosure, a harm that presumably benefits the public interest in information. Those grounds are almost always absent in behavioral science research, though there are exceptions, since behaviorists seek to protect all individual level data, both its source and any to whom the information applies.

Second, journalists are not now regulated by a requirement of informed consent much as is the case for behavioral scientists who do research in any public or private organization that lies outside the domain of government sponsored research. This leads to an imbalance in what information can be provided by whom, how, when and where. Were regulation to become unduly constraining for government sponsored research, that kind of inquiry might well shift to the private sector of behavioral science research and to the domain of journalists. Both shifts may have undesirable consequences. Were it to shift primarily to journalists, one would pay the cost that public information on many aspects of social life fall to their methods and procedures that lack the constraints of science. Were it to shift to the private sector, it might in the long-run jeopardize at least the study of government. One can think of other unintended and dysfunctional consequences as well.

Third, behavioral scientists have more of a stake in sharing confidential information for purposes of research than do journalists. Journalists do not ordinarily wish to share identifiable data; their sharing is done in the public press. Behavioral scientists thus have special problems of the transfer of identifiable data and its protection.

Need for Research on Informed Consent, Protection of Confidential Information, and their Regulation.

It is axiomatic that intelligent and enlightened regulation of biomedical and behavioral science research depends upon careful research on matters that are to be regulated. We cannot, for example, reasonably choose among modes of regulation without knowing a great deal about their consequences for free scientific inquiry--knowledge that must come, in part, from research. Now, it is paradoxical that once legal regulation is introduced it necessarily makes choices that constrain what investigators can do. Every form of emancipation carries with it its own form of enslavement. The consequences of regulation of behavioral science inquiry can be particularly destructive when they preclude or constrain unduly inquiry on processes of regulation and their effects on scientific inquiry. We shall briefly illustrate by several examples how this might easily be the case.

1. Were regulation to prohibit some forms of what is called "deception" in behavioral science inquiry, it would also preclude studying whether deception has the effects it is presumed to have and why, therefore, it was constrained. We very much need more knowledge on the effects of withholding certain kinds of information in securing consent from participants and of ways that such effects, if they may harm, can be altered to reduce substantially risk from harm. There are no other animals on which many features of social life can first be investigated.

2. Were regulation to preclude research on regulatory processes for behavioral research in any way, it will deny us that knowledge which we may need for intelligent regulation. A requirement that regulators grant their informed consent to be studied could well do just that. I note in passing that institutional sponsors and principal investigators perhaps have the

same rights to informed consent as all other participants in research. Should they be permitted to preclude many kinds of research on self-regulation because their informed consent is required?

3. It is axiomatic that any system of regulation or control generates its own forms of deviance. It must be so also with the regulation of scientific inquiry. The proper study of those forms of deviance among scientists will require their protection as participants if valid and reliable information is to be obtained on the "knowledge establishment". Knowledge of patterned evasion and other forms of deviation from the rules of regulation must be acquired for enlightened regulation.

I note in passing that much remains to be known about the organization of the production and dissemination of knowledge, about the role of government in research, including its regulatory processes, and about the effects of scientific inquiry on the participants in research. Acquiring that knowledge should not be constrained by regulation so as to subvert the very goals of enlightened regulation.

VI. EPILOGUE

A long dissertation--and this one perhaps needlessly so--has an end as well as a beginning. The medium is the message; yet redundancy is not altogether lacking in value. What is it that we have tried to say? Is there a cautionary tale?

This paper has treated of matters of regulating behavioral science inquiry by a requirement of informed consent. We have emphasized that informed consent is inextricably bound in behavioral science inquiry with the risks that attend disclosure or confidential information and stated the case for a need for the maximum possible legal protection for confidentiality. We likewise have emphasized that an elementary Human Subjects model of scientific inquiry is often inapplicable when applied to behavioral science inquiry; it perhaps often is so as well for bio-medical inquiry, depending upon how the line is drawn among disciplines.

Along the way, we have tried to maintain that some elements are more or less distinctive of behavioral science inquiry and how exceptions to these must be treated separately.

1. Behavioral scientists are interested in aggregative data for individuals, whether individual or corporate actors, not in individual level data. Exceptions arise for evaluation or assessment research, and their requirements may be different.

2. Behavioral scientists generally intervene in the life of participants only to acquire information from and about them; it is much less common that some form of intervention other than the research procedure is undertaken. Where it does occur, such as in experiments with human subjects and their collective life, separate consideration should be given to the problems that arise when a research role intersects with an inter-

vention role and to the consequences for research of deliberate intervention for purposes other than research.

3. Behavioral science inquiry is generally low risk inquiry so that for much of it a requirement of informed consent seems unnecessary and burdensome. The main risk from harm in behavioral science inquiry arises solely from the disclosure of confidential information, the disclosure being the source of harm. There is an obligation to protect participants from that risk of harm by disclosure, one that can be obviated by a legal privilege against compelled disclosure and by legal penalties for unauthorized disclosure, misuse, or illegal use.

Finally, we make note of the fact that legal regulation carries with it its own consequences that must be investigated by behavioral science inquiry if regulation is to be both enlightened and in keeping with constitutional imperatives. Regulatory constraints should make for as few constraints as possible in the study of the effects of regulation on free scientific inquiry, if in no other way than by making special provision for that kind of inquiry as an exception (and with due care for protection of all interests).

FOOTNOTES

1. There are some statutory limitations on consent where proprietary interests prevail or when exchanges are privileged.
2. The more unplanned the intrusion into private matters, the more complicated are problems of "informed consent" and "protection of the sources of information," matters treated below.
3. Note that I do not argue that we have a more legitimate claim to "truth," whether or not it is made in the name of scientific inquiry, but simply that our claim to science opens us to political challenge.
4. The concept "written consent" applies to more than that it be written (one has an option to read it). The operable condition is that it be a signed consent to a written statement that is read either by participants and/or their representative(s) or by the investigator/agent. In this sense "signed written consent" is a more meaningful designation of these procedures for obtaining informed consent.

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THREE THEORIES OF INFORMED CONSENT: PHILOSOPHICAL
FOUNDATIONS AND POLICY IMPLICATIONS

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February 2, 1976

Abstract

To understand the nature and definition of informed consent it is essential to understand the reason why we get consent in the first place. This paper outlines three alternative theories of informed consent. First, consistent with the traditional Hippocratic ethic of the medical profession, informed consent may serve the purpose of protecting subjects from harm. That current DHEW regulations require assuring informed consent only when subjects are at risk implies that this may be the foundation. However, if the objective is to protect subjects from harm this could be accomplished more efficiently by simply banning all non-therapeutic research. Furthermore, one must understand why one would be committed to protecting individuals from harm. It is suggested that it is because individuals are the possessors of individual rights including the right to self-determination.

A second theoretical foundation for informed consent might be the classical utilitarian one: the greatest good for the greatest number. If the research enterprise depends on continued trust and confidence from the public, then consent might, in the long run, produce the greatest good by helping maintain the public trust in the medical research community. The difficulty with the second theory, however, is that it justifies too much. Often it might be the case that even greater good would be done if no consent were obtained and the rights of the individual were subordinated to the good of society. Once again a commitment to the rights of the individual requires that limits be placed on arguments based solely on consequences.

The third theoretical foundation for informed consent we believe to be the most plausible one: the individual's right to self-determination. This right, basic to Western society and American political philosophy in particular, implies that invasion of the individual's body or privacy requires an informed consent. The consent cannot be dependent upon the claim that good consequences can come for the individual or society if the consent is obtained.

Next the implications of the self-determination theory of consent for the standard of consent--for determining how much information must be transmitted for consent to be adequately informed--are examined. It is suggested that while if consequences were the foundation of consent professional standards might (but not necessarily would) be acceptable, the principle of self-determination requires the reasonable person standard now being incorporated into informed consent court cases in many jurisdictions. This standard must be modified, however, when there is evidence the subject wants more information than the reasonable person. The practical implication is that for purposes of approval of the adequacy of the consent (and for judging whether the risks to the subject are justified by the potential benefits to the subject and/or others) an all lay committee of "reasonable people" is the only reliable basis of judgment. An advocacy system for introducing technical information to such a lay committee is proposed.

The implications of the self-determination theory of informed consent for Group I (competent, noninstitutionalized adults receiving medical care through private sources) are traced. It is suggested that only research protocols which would themselves compromise the subject's future capacity to consent should be prohibited by a review committee. For Group II subjects (those whose capacity or opportunity to consent is more problematic), however, self-determination may be impossible (small children, the comatose), compromised (older children, the mentally incompetent), or de facto restrained (prisoners, clinic patients, and subjects of experiments where consent would destroy the research). Group II subjects should normally be used only when it is impossible to use Group I subjects.

The question of overriding the principle of self-determination in cases where consent would destroy the experiment is considered concluding that only the principle of self-determination itself provides a workable ground for waiving consent. The only other possible ethical grounding--a non-utilitarian theory of justice--may eventually provide an additional basis, but only when the application of the theory to medical experimentation is further developed. A national level review is proposed for any use of Group II subjects.

Specific Recommendations

1. The individual's right to self-determination should be recognized as the foundation of the requirement for informed consent.
2. The present DHEW policy of requiring legally effective informed consent only if risk is involved should be abandoned.
3. The "reasonable person" standard for judging the adequacy of consent should be formally recognized, except in cases where there is evidence that the individual subject would require a different level of information in order to exercise what he or she considers self-determination.
4. An advocacy system of IRB consideration of protocols including adequacy of proposed consent forms should be adopted.
5. The following additional items should be included in the current list of "basic elements" of an informed consent:
 - a. A specific disclosure of the presence of a control group within the research design.
 - b. A statement of the inconveniences as well as the risks and discomforts.
 - c. Names of review and patient protection agents at the local and national level.

- d. A statement of the basic rights of the subject.
 - e. An explanation of who, if anyone, will be responsible for harms done.
 - f. An explanation of the right, if any, to continue receiving treatments found helpful.
6. The words "for negligence" should be deleted from the exculpatory language prohibition.
 7. The "short form" of written informed consent in which a subject signs a statement that the information has been transmitted orally should be abandoned.
 8. The researcher or their staffs should never be expected or permitted to obtain the consent themselves. A specially trained individual not directly involved in the research should have that task.
 9. Experiments on Group I subjects with free and informed consent should not be disapproved unless they would compromise the subject's future ability to exercise self-determination.
 10. The term "proxy consent" should be abandoned. Parent or guardian "selection" or "approval" should be required for therapeutic research on children. Parents should have discretion within the limits of reasonableness to decide what should be counted as potentially therapeutic for their wards.
 11. Parents or guardians should be permitted to approve non-therapeutic research on their wards whenever the research meets rigid criteria including no or minimal risk to the subject.
 12. Children and formerly competent patients should be able to exercise self-determination to rejecting non-therapeutic experiments.
 13. The formerly competent patient's wishes clearly expressed while competent should be determinative when the patient is no longer competent.
 14. Children and formerly competent patients should be able to exercise self-determination in accepting or rejecting therapeutic experiments and accepting non-therapeutic experiments if they are judged by a court to understand sufficiently the nature of the choice.
 15. Prisoners should not be treated as in any way having lost their capacity for self-determination.
 16. In cases where the de facto opportunity for prisoners to exercise self-determination is diminished because of the nature of the institutional structure, this should be seen as a fault of the prison system, not of the prisoner.

17. A scheme should be considered whereby prisoners are compensated for research at rates comparable to other prison wages proportionate to time and risk while those doing research pay at a rate comparable to costs to obtain similar subjects outside the prison. The difference should be made available to the prison population for educational and recreational activities.
18. Clinic patients should be treated as Group II subjects. It should be required that at least half of all subjects be recruited from other than clinic patient sources.
19. In experiments where informed consent would destroy the research informed consent should nevertheless be required unless it can reasonably be presumed with at least a 95 percent level of certainty on the basis of specific empirical evidence obtained from mock-subjects drawn from the same subject population that the real subjects would not consider their uninformed participation a violation of their right to self-determination.
20. More research should be undertaken on the adequacy of a non-utilitarian theory of justice for providing a criterion for overriding consent in specific cases where those less well off than the subject would benefit greatly.
21. A special, second review at the national level of the quality of the consent (and the acceptability of the risk) should be required for all use of Group II subjects to assure that self-determination is preserved to the extent possible and that only reasonable risks are taken when self-determination is not possible.

Current government regulations require local review of all biomedical and behavioral research on human subjects supported under grants and contracts from the Department of Health, Education, and Welfare to determine whether subjects will be placed at risk and, "if risk is involved," whether "legally effective informed consent will be obtained by adequate and appropriate methods."¹ The logical implication is that informed consent of human subjects, insofar as it is mandated by DHEW regulations, is subordinated to and derivative from the goal of protecting human subjects from risk. If that is the case I believe the current requirement of informed consent rests on an inadequate base.

My objective is to analyze the philosophical foundations of informed consent articulating three theories of informed consent and the implications of those theories for public policy. I shall argue that informed consent in its essence cannot be related to and derived from the notion of avoiding risks and/or producing good consequences, but must have an independent philosophical foundation. That foundation, so I shall argue, is the principle of autonomy--of self-determination. After exploring the three competing theories of informed consent, I shall then examine the implications for deciding how much information ought to be transmitted for consent to be informed. Finally I shall trace some of the policy implications first for informed consent from competent, non-institutionalized subjects and then for subjects who are legally incompetent, institutionalized, or both.

I. THREE THEORIES OF INFORMED CONSENT

My assigned task is to discuss the nature and definition of informed consent. Although I am to focus on informed consent in various research settings, I am convinced that the same standards apply to clinical medicine. Thus some reference to cases and argument dealing with routine clinical care will be made.² Also it might be appropriate to broaden that task slightly to discuss free and informed consent. That consent be both free and informed within certain limits seems necessary to make a consent adequate.³ It is important to realize how modern any notion of consent is whether or not it is qualified by the requirements that it be free and informed. In order to develop a theory of the foundations of consent it is essential to place the concept in a historical context.

A. The Patient Benefit Theory of Informed Consent

Traditionally experimentation in medicine was an integral part of the treatment of the patient. The Hippocratic authors placed medicine on a more naturalistic footing. In works such as The Sacred Disease the Hippocratic corpus demystifies diseases such as epilepsy.⁴ The author argues with regard to epilepsy, which had at the time been interpreted as being caused by sacred powers, that "It is not, in my opinion, any more divine or more sacred than other diseases, but has a natural cause, and its supposed divine origin is due to men's inexperience, and their wonder at its peculiar character."⁵

In spite of the fact that Hippocratic and Galenic medicine viewed medical problems as natural phenomena, these traditions did not rationalize

and systematize medical experimentation as we know it. This did not happen until modern times--the end of the eighteenth century. The Hippocratic physician would try out new remedies, but always in the context of treating a patient when routine therapies were not successful. It was not until well into the modern period that medical experimentation was undertaken in the sense of systematically designed research for the purpose of gaining medical knowledge. It is in part for this reason that consent is absent from the Hippocratic tradition.

The ethic of the Hippocratic physician was (and to some extent still is) rooted in a special set of norms. According to Ludwig Edelstein the deontological (ethical) writings of the Hippocratic corpus reflect the philosophical, religious, and scientific views of the Pythagorean cult.⁶ The dominating ethical norm is that the physician's duty is to do what will benefit the patient according to his ability and judgment.⁷

Although the modern physician may not have read the Hippocratic Oath recently, the ethical norms are ones with which he is comfortable. The World Medical Association in 1949 adopted an International Code of Medical Ethics which includes an updated version of the patient-benefitting principle: "Under no circumstances is a doctor permitted to do anything that would weaken the physical or mental resistance of a human being except from strictly therapeutic or prophylactic indications imposed in the interest of his patient." It is generally thought that the Hippocratic Oath may be rather platitudinous. It is usually not recognized how controversial the principle itself is.⁸ For our purposes the primary implication is that all physician activity in-

cluding medical experimentation which is not undertaken for the benefit of the patient ought to be forbidden.⁹

Although the requirement of informed consent is not traditional in Hippocratic medicine, it is possible to justify such a requirement on patient-benefitting grounds. Indeed, if we recognize that judgments about what is beneficial to a particular patient will vary from patient to patient depending upon the particular norms and values of that person, a strong case can be made that informing patients of treatment alternatives so that they can participate in or even control the decision-making process will increase the likelihood that patient-benefits will be maximized. Especially in cases of what might be called therapeutic research,¹⁰ that is research which simultaneously has two objectives, pursuit of knowledge and potential benefit to the patient, patients might plausibly maximize benefits by choosing between more conservative, standard therapies and experimental therapies on the basis of their own inclination to take chances and their faith in technological innovation.¹¹ Thus even in classical Hippocratic ethics informed consent may have an importance place.

The decisive case for testing the relationship between patient-benefit and informed consent ought to be the special situation where someone (usually the physician) believes that getting patient consent will do harm to the patient rather than produce benefit. Testing a psychoactive compound for the treatment of schizophrenia is an example. Testing an experimental cancer drug on a terminally ill patient who does not know his or his diagnosis or prognosis is another. If informed consent is a derivative princi-

ple designed to insure patient benefit, then whenever getting consent would do more harm than good it ought to be waived. This exemption is explicit in the 1971 FDA regulations for consent for use of an investigational new drug. Consent is to be obtained except where the investigators "deem it not feasible or, in their professional judgment, contrary to the best interest of such human beings" (i.e. the subjects).¹² It is implied in the December 1, 1971, version of the DHEW Guidelines. Citing the important Halushka vs. University of Saskatchewan case, the guidelines specify that:

Where an activity involves therapy, diagnosis, or management, and a professional/patient relationship exists, it is necessary "to recognize that each patient's mental and emotional condition is important...and that in discussing the element of risk, a certain amount of discretion must be employed consistent with full disclosure of fact necessary to any informed consent."¹³

The draft regulations as revised and published in the Federal Register October 9, 1973,¹⁴ and the final regulations as published May 30, 1974,¹⁵ also have no such exclusion. There are two possible explanations. First, the drafters of the regulations may have continued in their commitment to patient benefit, but held that consent will, on balance, be a practice which is patient-benefitting in the sense of protecting them from risk even in those cases where researchers believe that the patient would be benefited more by not being told.¹⁶ If physicians were not capable of perceiving what would benefit the patient--in terms of the patient's own values--or what the patient's response to the request for consent would be, then the consent should be obtained even if, in the physician's judgment, it might

do harm.¹⁷ Alternatively they may have held that informed consent is so fundamental to the subject's rights in the therapeutic experiment that it must be retained even in cases where the physician (rightly) perceives that it might do more harm than good.¹⁸

We are left with a confusion in the current guidelines. Consent is only required in cases where subjects have been found to be at risk implying that consent is somehow inherently linked with and subordinated to the primary goal of protecting patients from harm. On the other hand the researcher and the local committee are not permitted to waive consent on grounds of net patient-benefit.

More doubt is cast on the adequacy of the patient-benefit grounds for informed consent when one realizes that the patient-benefit principle traditional in medicine would rule out entirely all non-therapeutic experiments that is experiments designed to gain knowledge useful to society, but with risks not justified on patient-benefitting grounds alone. It is clear that any physician who holds to the principles of the Hippocratic Oath cannot participate in any non-therapeutic research. To do so would be to act other than strictly for the benefit of his patient.

The standard of the Hippocratic ethic, however, is the standard of a private, professional group. The ethical principles of private groups including medical groups ought to be of minimal importance to the National Commission for the Protection of Human Subjects. It is the purpose of the Commission to determine an ethically acceptable basis for human experimentation whether or not that basis is consistent with the ethical view of

any such private groups. Nevertheless it is of interest that the medical profession itself has abandoned its sole commitment to patient-benefit when it considers non-therapeutic experimentation. In 1954, five years after its general reaffirmation of the patient-benefitting principle as the old grounds under which a physician could do anything to weaken the physical or mental resistance of a human being, the World Medical Association adopted its "Principles for Those in Research and Experimentation" which clearly approves research on healthy subjects. By 1962 in the Declaration of Helsinki the World Medical Association explicitly adopts a principle approving of non-therapeutic experiments "because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity." The American Medical Association has similarly approved of non-therapeutic research implying that it too has abandoned the Hippocratic or patient-benefitting ethic as its decisive norm.

Of primary importance to the National Commission, however, is not the norms of private groups including professional groups, but publicly legitimated and accepted ethical standards. In one sense the Commission's task is the protection of human subjects. Clearly the easiest way to protect human subjects would be to ban all non-therapeutic research. Consent might be justified for therapeutic experiments on patient-benefitting grounds, but it is not clear that consent should always be required even in those experiments. It would be required when, and only when, patients would be more likely to benefit by giving consent.

I take it as accepted by the Commission and by most reasonable people in our society that at least some non-therapeutic experimentation is acceptable. If that is the case, however, the sole task of the Commission cannot be the protection of human subjects. Likewise the sole foundation of informed consent cannot be patient-benefit. In fact when patients consent for non-therapeutic experimentation, and for much therapeutic experimentation as well, consent seems to function more to cancel the implicit obligation of the physician that he will strive only to benefit the patient and protect him from harm. Logically, if consent functions to waive the obligations of the norm of patient-benefit, it cannot itself be grounded in patient-benefit.

Since the logical implication of the patient-benefitting principle--that research can be done only for the benefit of the individual patient/subject--is strongly counter-intuitive, that awareness may be sufficient to reject the patient-benefitting principle as the foundation of informed consent. The principle itself, however, implies even better reason. One should ask why it is that physicians or others would feel a duty to act only so as to benefit the patient and protect him or her from harm. It seems the most plausible answer is that the individual human being (who is sometimes in the patient role) is seen as an autonomous entity with special claims against the rest of us--claims normally called rights. This awareness that the individual human is uniquely endowed with rights is variously expressed in the Western tradition by saying that humans were created in the image of God (Genesis), are to be treated as an end and never only as a means (Kant), or simply that they are endowed by their Creator with

certain inalienable rights. If, however, the individual person is always to be treated as an end and never only as a means, it must mean more than that simply others must avoid taking risks with that individual. To be a person is to be an autonomous individual, the possessor of rights.

This notion of the human as an autonomous individual who is the possessor of rights is not explicit in the patient-benefitting Hippocratic tradition. In fact, the explicit notion of individual rights is, like the principle of informed consent, uniquely modern. It is understandable that modern medical professionals who remain Hippocratic in their ethic would tend to link consent to risks and benefits for the patient. For those more explicitly committed to individual rights, however, that Hippocratic view limited to benefits and risks to the patient will be an inadequate foundation for the patient-physician relationship. It will be even less adequate for the relationship between researcher and subject.

B. The Social Benefit Theory of Informed Consent

If it seems implausible that the primary purpose of informed consent is to protect patients against risk--although it may in some instances function in this way--some may find its purpose in the more generally accepted ethical theory of utilitarianism. According to this view, as articulated by Bentham, Mill, and others,²⁰ that course of action is right which produces the greatest good for the greatest number. Experimentation would be justified according to this view if, all things considered, more good than harm came from the experiment and more net good came from the experiment than any other plausible course of action. Holders of this view are

sophisticated in recognizing that good cannot be limited to economic considerations. Aesthetic, cultural, religious, and psychological goods and harms would have to be taken into account. The deprivation of liberty to a small group of subjects would not necessarily be justified by great goods to a great number of others provided that one counted the deprivation as a very grave harm.

If non-therapeutic experiments are to be justified at all, there almost has to be some element of social benefit included in the justification. As long as experimenting in medicine was in the context of patient care, that is when experiments were therapeutic in intent, social benefits of the research were ancillary. With the modern period, however, when rational design of research in the pursuit of knowledge gave independent grounds for experimenting, benefits to others became significant and at the same time introduced a potential conflict with the benefit-to-patient norm.

It is often not realized how modern a phenomenon systematically designed experimentation is. Experimental medicine is often dated from William Harvey's publication of his studies of animal circulation in 1628.²¹ While this work exemplifies research for the pursuit of knowledge, even this did not involve systematically controlled research exposing human subjects to such risks as double blind placebo administration. Systematic investigation of this kind is a nineteenth and even more a twentieth century phenomenon.

By the beginning of the nineteenth century research for the good of society rather than the individual patient began to be defended. Thomas Percival was asked by the trustees of the Manchester Infirmary to prepare a code of ethical conduct for physicians to help them overcome an internal dispute. The Code, which was published in 1803, has become the foundation of Anglo-American physician ethics. In the document Percival is explicit in justifying medical experimentation on broader public benefit grounds:

Whenever cases occur, attended with circumstances not heretofore observed, or in which the ordinary modes of practice have been attempted without success, it is for the public good, and in especial degree advantageous to the poor (who, being the most numerous class of society, are the greatest beneficiaries of the healing art) that new remedies and new methods of chirurgical treatment should be devised. But in the accomplishment of the salutary purpose, the gentlemen of the faculty should be scrupulously and conscientiously governed by sound reason, just analogy, or well authenticated facts. And no such trials should be instituted without a previous consultation of the physicians or surgeons according to the nature of the case.²²

There is not any hint of a patient consent requirement, but there must be previous consultation with "the gentlemen of the faculty." Given the context of the tensions at the Manchester infirmary at the time it is plausible to see this consultation as serving more general social purposes including protection of the hospital's image as well as making sure that the experimentation is "for the public good, and in especial degree advantageous for the poor."

In Claude Bernard, the father of modern medical experimentation, the justification of experimentation in terms of the general good it will do

goes even further. In his famous Introduction to the Study of Experimental Medicine in 1865 he boldly claims that "Christian morals forbid only one thing, doing ill to one's neighbor. So, among the experiments that may be tried on man, those that can only harm are forbidden, those that are innocent are permissible, and those that may do good are obligatory."²³

The question remains, if the underlying justification of medical experimentation is that it will produce good social consequences on balance, what is the place of informed consent? For the most part it would appear that more research could be done more efficiently to produce more good consequences if the consent requirement were eliminated. There is one justification for the consent requirement, however, even on social benefit grounds. It may be that a general policy of research for social good without patient or subject consent would soon create public suspicion and severe handicap for the research enterprise. Subjects would resist situations where experiment was likely. A requirement that all subjects must give consent would assure lay people that they would not be unknowing subjects of medical research. The general consent rule might simply be a clever way of promoting long run social utility.²⁴ The fact that social usefulness of information per se is sufficient to make consent expendable requires some commitment to a social utility theory.

A test case would be an experiment which, by its very nature could not be done with consent, for example psychological studies of perception. Under these circumstances no good could come if consent were obtained, while some good might come if the research were permitted under controlled

non-consent circumstances. The social utility theory of consent is supported by the fact that current DHEW guidelines permit waiving of the consent requirement when "that use of either of the primary procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance."²⁵

There is some evidence that the original introduction of consent for research in the nineteenth century had as one of its purposes the preservation of the research for the social good which could come. In 1822 William Beaumont began his famous experiments on gastric physiology. His work was made possible because one Alexis St. Martin suffered an accidental shotgun wound leaving a fistula (a direct opening) to the stomach. St. Martin signed a written contract with Beaumont agreeing to be his "covenant servant" for one year.²⁶ St. Martin was destitute and destined to be deported as an alien unless he could find some way to support himself. His agreement with Beaumont was the solution. Its quality is primitive by late twentieth century standards. Being a binding agreement it seems in part designed to guarantee that once Dr. Beaumont had invested in the subject, St. Martin would continue with him until the results could be demonstrated to his colleagues.²⁷

While there are instances where the consent seems to function to serve the general social welfare rather than protect the patient, for the most part that does not seem to be its primary purpose. In fact while, in contrast to the patient-benefitting principle, the principle of social benefit legitimates non-therapeutic research, it seems to legitimate too

much. According to the principle, research which will on balance serve the general welfare must be done. Only in cases where the consent facilitates the research would it be necessary.

It is the social benefits principle which, together with some strangely ethnocentric values, led to the Nazi experiments and the decisive challenge to the bonum commune defense of medical experimentation.²⁸ It became clear at Nuremberg as never before that fundamental human rights were at stake in non-therapeutic research justified on the grounds of the greater good for society.

C. The Self-determination Theory of Informed Consent

If maximizing social benefits leads to unacceptable violation of the rights of the individual subject, the drafters of the Nuremberg Code had two options. They could return to the older Hippocratic formula insisting the research be undertaken only when it is justifiable in terms of benefit to the patient/subject. Alternatively they could hold to the legitimacy of research for the good of the community and control against excesses by articulating some limiting principle. The authors chose the latter course. The second principle of Nuremberg makes clear that social benefit has not been abandoned.²⁹ But informed consent is introduced as the first principle clearly not to facilitate social benefits, but as a check against them.³⁰ We are led to an inescapable conclusion. Anyone who imposes an informed consent requirement on medical research for a reason other than the instrumental value that consent might have in furthering research for the common good must recognize that individual subjects have claims against the society,

claims so strong we call them "rights." There must be rights of the individual which have standing even against the claim that the greater good would be served if those rights were compromised.

This should not sound strange at least for one steeped in Anglo-American political philosophy. Americans have learned that all are endowed by their Creator with certain inalienable rights including life, liberty, and the pursuit of happiness. The Constitutional guarantee to due process before deprivation of liberty cannot be sacrificed simply because the good of the community would be served.

Although informed consent may, upon occasion, promote benefits to the patient and/or benefits to society, it is clear that its primary purpose stands over against these consequentialist objectives. Informed consent functions as a waiver of certain individual rights for the good of self (patient/subject benefit) or others (social benefit). In particular it is the individual's right to self-determination which makes informed consent necessary for all invasions of the body or even invasions of one's privacy. The principle of autonomy--the right to self-determination--provides an independent foundation for the informed consent requirement, a foundation much more solid than the justifications of informed consent which occasionally can be derived from concern over protection of the individual against risk or protection of the society by protecting the larger research enterprise. It is because of this self-determination foundation that consent giving can be seen as a negotiation of a contract.

There is strong legal evidence that this self-determination theory of informed consent is the philosophical foundation of the consent requirement. It was not always the case in American jurisprudence, however. As late as 1871³² and again in 1895³³ major court opinions dealing with experimentation omitted any requirement for consent. But in 1914 Justice Cardozo articulated forcefully the patient's right to self-determination as the basis for surgery:

...Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.... This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained....³⁴

The self-determination principle was reaffirmed as the foundation of that consent clearly in the famous *Natanson v. Kline* in 1960 where Justice Schroeder argued:

Anglo-American law starts with the premise of thoroughgoing self-determination. It follows that each man is considered to be master of his own body, and he may, if he be of sound mind, expressly prohibit the performance of life-saving surgery, or other medical treatment.³⁵

The principle of consent was applied to experimentation as opposed to routine treatment in *Fortner v. Koch*³⁶ in 1935.

There is some evidence that the authors of the DHEW guidelines recognize that informed consent as well as other rights are independent of the question of risks and benefits to subject and society. Whenever review is

mandated, review committees have three substantive tasks: to determine that (a) the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks; (b) the rights and welfare of any such subjects will be adequately protected; and (c) legally effective informed consent will be obtained by adequate and appropriate methods.³⁷ That there are three co-equal requirements of review makes clear that the right to consent as well as the other "rights and welfare" mentioned in clauses (b) and (c) are not derived from the notion of risk to the subject. If they were it would be more appropriate to say that the review committee must see that the risks to the subject including violations of rights are so outweighed.... The DHEW guidelines follow traditional theories of rights in American political philosophy by recognizing that rights of individuals including the right to consent are independent of consideration of risks.

Yet if that is so it is paradoxical that (b) and (c), that is the protection of rights including the right to consent, are to be assured by review only in cases where the subject is at risk. Logically it would make sense to require that a determination of risks is sufficiently outweighed by potential benefits only in cases where subjects are at risk, but it is fundamentally illogical to require that the rights of the subject are to be protected only in cases where the subject is at risk.

If it is correct that the principle of self-determination is the proper foundation of a theory of informed consent and that rights of subjects

exist independent of consideration of risks and benefit, then there seems to me to be only one possible explanation of the subordination of determination of protection of subject rights to the determination that the subject is at risk. To make this clear let me suggest two forms the notion of self-determination might take as a basis for informed consent.

The first I would call the weak theory of self-determination. According to this view an individual has the right to self-determination regarding invasion of his body or his privacy only when exercising that self-determination will materially affect his welfare. In this case an individual's right to self-determination is limited to the area of risk-taking. On the other hand we might speak of a "full theory of self-determination." If an individual is always to be treated as an end and never only as a means, that individual is the possessor of autonomy in all areas of his life, not simply in cases where material risks and benefits are at stake. In fact at least within limits we shall consider below he possesses the right to self-determination to make choices which are contrary to his own interests. Put in these terms it seems most implausible that the rights of life, liberty, and the pursuit of happiness would carry the proviso "only in circumstances when risks and benefits are involved." Many of the cases where one exercises the right to self-determination are cases where risks and benefits as we normally think of them are not at stake. The constitutional rights to liberty and privacy cannot be so limited that they only apply in cases where a committee has determined that the subject is at risk. The right to confidentiality for instance, which is normally subsumed under (b) can not be conditional on the subject's being at risk.

If one examines the list of basic elements of informed consent one discovers that some of the items included are not directly linked to subject's calculation of risks and benefits. For instance, suppose human blood were needed to develop a test for sickle cell anemia and trait in fetuses. Blood samples are to be obtained from adults with and without sickle cell disease or trait for purposes of developing the test. The eventual objective of the research is to develop the diagnosis in time so that all fetuses with disease or trait could be aborted thus improving the gene pool. If the blood were obtained as remainder blood from routine diagnostic work, it is difficult to conceive of any risk to the subject in having it used in the study. He will never be at risk to be aborted as a fetus and, if he already has reason to believe he and his spouse do not have the disease or carrier status, his offspring could not even be affected in any direct manner.³⁸ Yet it seems that some people might object to the purposes of this research. Still more might object to having their blood used for this study without their consent. That presumably is why the first basic element of informed consent includes a fair explanation of the purposes of the research.³⁹

A second example of a piece of research where no plausible risk to the subject is at stake and yet subjects might plausibly want the opportunity to consent to the research involves a study using human placentas for basic physiological study. Placentas normally routinely discarded in the delivery room would be salvaged for research purposes. It could plausibly be argued that the women from whom the placentas were taken were not at any risk from the study. They were not being asked to modify the

delivery procedure at all. Yet it seems plausible that many women would want to be told that the placenta was to be used in this manner. Some may object; others would gladly consent--if they are given the opportunity.

A third example is the patient studies with medical instructions mentioned by Levine.³⁹ Even if one had no reason to fear direct risk of ridicule, one might plausibly object to the concept of "compliance" on the grounds such research is often built on the unstated hypothesis patients are wrong in their judgment not to follow medical advice (or doctor's orders). If one believed that such patient judgments were often rational given the value system and world view of the patient, but also that those studying "compliance" did not share that belief, then one might want to refuse to participate in such compliance studies on the grounds that they were misguided, had the potential of leading to erroneous conclusions, and, if nothing more, paternalistic in their conception. Such a patient might reasonably want the opportunity to participate in such studies because he or she objects to the purpose of the study rather than the risks.

Even the use of autopsy material and severed organs and limbs for research raises questions which certain individuals would find potentially meaningful or useful. For instance Orthodox Jews might object on theological grounds to autopsy and subsequent research use unless they were directly linked to the saving of a particular life.⁴⁰ Objections to the purpose of the research as well as idiosyncratic objections based on unique systems of belief and value can be made independent of risk/benefit considerations.

The point is a logical one: if the right to self-determination is the proper basis of the consent, it is illogical to make the exercise of that right dependent upon the subject's being at risk.

II. THE STANDARD OF REASONABLY INFORMED CONSENT

If the proper theoretical foundation for informed consent is the principle of self-determination or autonomy, this ought to have implications for our understanding of informed consent in various research settings. Before looking at those implications for specific settings I want to connect this self-determination theory to a question which has received much attention recently in the legal literature: the question of the standard to be used in deciding how much information ought to be transmitted for a consent to be informed.

Before looking at some plausible alternative answers it is necessary to put aside one red herring, the standard of "fully informed and free consent." Researchers sometimes argue that it is impossible to give the subject enough information for consent to be "fully" informed.⁴¹ To do so would require an infinite amount of information--or at least a full medical education. Since consent cannot be fully informed, they argue, the physician should select particularly important items to transmit, but not strive for an impossible standard.

I claim this is a red herring because no one, or at least no one who has thought about it, really demands "fully" informed consent. It is not only impossible, but would be terribly tedious. It is more plausible

to require that all potentially useful or meaningful information be transmitted. I say meaningful as well as useful since, as in the case of the placentas, some information might be seen as meaningful even if no concrete use can be made of it.

We are still left with the question of how much information ought to be transmitted if the standard is that which is potentially useful or meaningful? Most believe that the traditional standard was some variant on the standard of the profession: what the reasonable physician would have disclosed under the circumstances.⁴² The court case which is often cited is *Natanson v. Kline*, especially the qualification that:

The duty of the physician to disclose, however, is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances. How the physician may best discharge his obligation to the patient in this difficult situation involves primarily a question of medical judgment... the physician's choice of plausible courses should not be called into question if it appears, all circumstances considered, that the physician was motivated only by the patient's best therapeutic interests and he proceeded as competent medical men would have done in similar circumstances.⁴³

The standard of the profession has been challenged widely in court cases in ten states⁴⁴ and in many articles in legal journals.⁴⁵ I presume that this legal development, which I take to be the most exciting theoretical conceptual shift in the ethical and legal dimensions of medicine in the twentieth century, will be thoroughly discussed in the legal documents on informed consent being prepared for the Commission. My task is to point out the philosophical implications and the connection of this shift to the

three theories of consent I have developed.

From Justice Schroeder's opinion in Natanson v. Kline it appears that patient-benefit is an underlying concern for setting the standard of how much information is to be transmitted. The physician is to be motivated only by the patient's best therapeutic interests. Even if one assumes that patient-benefit is the primary foundation of informed consent--an assumption which we have challenged and which would rule out all non-therapeutic experiments--it would still be necessary to make further assumptions in order for the standard of the profession to be used in determining how much information must be transmitted. It would be necessary to assume that the physician or physician/researcher was the proper person to determine what is in the patient's best interest.

This presumption appears to rest on an old model of medical decision-making, one which sees medical choices as essentially technical matters based on the scientific skills of the physician. If we can presume that the values underlying the decision are agreed upon and the only question is which course would promote the desired end, then those with technical competency would appropriately be able to decide what would be in the patient's interest.

It seems clear, however, especially in cases where the patient is to choose between a conservative approach using an established therapy and a more innovative course with an experimental therapy, that we cannot agree on the values underlying the decision.

If consent for experiments were based upon either subject-benefit or broader societal-benefit and we can assume there is some expert in deciding what is beneficial other than the subject himself, then it would be plausible to limit the information transmitted to those items which the expert considered necessary in deciding what would be beneficial. Thus, apparently beginning from a patient-benefitting motive, Garnham proposes substitution of a physician's informed judgment for that of the patient's.⁴⁶

Even if this were the theoretical underpinning of the consent, however, it is unlikely that the medical professional would be the appropriate expert at least unless he had sufficient psychological skills to decide what would benefit and what would harm. In cases of consent for experimentation the subject-benefitting consideration which might require getting consent or place limits on getting that consent is primarily the psychological benefits to the patient/subject. If the patient/subject would be distressed at not knowing what was being done then consent should be obtained. If the patient/subject would be distressed at hearing the details of the research or its purposes then it should not be--according to this theory. But it would normally be psychological experts who could most appropriately make that judgment. If, on the other hand, consent is rooted in a bonum commune defense, then the appropriate expert would be someone such as a sociologist skilled at judging community sentiment about the research enterprise. In neither case would the (non-psychiatric) physician have the relevant skills.

If the theory behind informed consent is the individual's right to autonomy or self-determination, however, then the appropriate standard for how much information should be transmitted should not be related to any of these professional skills. The standard ought to be the amount of information necessary for the subject to exercise self-determination, that is the amount of information the subject would find useful or meaningful, independent of whether the researcher or the research community would find that information useful or meaningful.^{46a} If the objective of the consent is to promote self-determination, then it is the subject population itself which must provide the standard for determining how much information is to be transmitted in order to exercise self-determination.

Earlier I said, with regard to the Natanson v. Kline case that most believe that this case puts forward the traditional standard of the profession. In fact a close reading of it reveals it is much closer to the reasonable person standard than most realize. In the earlier quotation a key phrase was omitted, one which is often overlooked. It says the standard of the profession is to be used in judging the adequacy of information "So long as the disclosure is sufficient to assure an informed consent." The fact that the patient benefitting criterion and the standard of the profession are specifically qualified in this way suggests that Judge Schroeder must have had something more in mind.

This shift to lay standards--determining what the reasonable person would want to know before consenting to research or therapy--is now be-

coming the basis for judging whether a consent is informed. The "reasonable man" (or "reasonable person") standard is now explicit in court cases in many jurisdictions beginning with *Berkey v. Anderson* in California in 1969 in which it was argued that:

We cannot agree that the matter of informed consent must be determined on the basis of medical testimony any more than that expert testimony of the standard practice is determinative in any other case involving a fiduciary relationship. We agree with appellant that a physician's duty to disclose is not governed by the standard practice of the physicians' community, but is a duty imposed by law which governs his conduct in the same manner as others in a similar fiduciary relationship. To hold otherwise would permit the medical profession to determine its own responsibilities...⁴⁷

There are radical implications for local experimentation committees of the reasonable person standard for determining how much information is necessary for consent to be informed. I have recently completed a study of those implications, the full text of which is available for the Commission's use.⁴⁸ Here I shall summarize the conclusions. One task of such committees is to determine if legally effective informed consent will be obtained. If, however, self-determination is the foundation for making that decision and therefore the reasonable lay person's judgment is necessary for deciding how much information that is, then a committee which is skewed in its composition away from that representative reasonable lay person will not be capable of deciding whether the consent proposed is adequate. If committees include research scientists in greater proportion than in the general public and those research scientists predictably give atypical answers to such questions as whether they would want to know certain information and whether

the risk is "worth it" given the potential benefits of the knowledge, then such committees will give predictably unreliable answers to such questions. It is not just that the committee must include some lay representation. Rather in order to adequately carry out this one particular function of deciding what the reasonable lay person would want to know, the committee must be made up entirely of lay people (or alternatively composed in such a way that special professional biases are neutralized). Of course, for other functions, such as establishing the risks, professional skills are needed. This remains a fundamental dilemma which, as I see it, can only be resolved by having two committees, (one lay, the other professional) or by reducing professionals to a strictly technical advisory capacity. The capacity of lay people to make such judgments and the fact that those judgments differ from professionally staffed IRB's is documented by Norman Fost's study of a "surrogate system" for informed consent.⁴⁹ His proposal differs from mine in that the lay people would not actually function as a committee.

Even if those with special medical skills and the unique value commitments which accompany those skills are limited to the role of technical advisors to an all lay committee, there is reason to doubt that it is even theoretically possible much less practical to transmit information to the committee in a "neutral" manner. Perhaps we should consider shifting to the advocacy system for such review of protocols. Under such a system technical staff selected purposefully because of their inclination for and against the research enterprise would be charged with the tasks of presenting the best technical cases for and against the protocol under consid-

eration. The lay committee, having heard the cases would, after an opportunity to request further information and explanation, exercise their judgments as reasonable people about the adequacy of the consent (and presumably also whether the risk to the subject was justified by the potential benefit to subject and/or others).

There is one additional problem with the use of the reasonable person for assuring that subjects will receive the information they consider useful or meaningful. What of the subject who is "unreasonable" in the technical sense the term "reasonable" is used in the law? What of the subject who desires more or less information than the reasonable person? If the goal is providing enough information for adequate self-determination, surely the reasonable person standard is not adequate for such subjects. If there is any reason to believe that the particular patient or subject wants more information than the reasonable citizen, then the patient or subject's own standard of certainty must apply. If a subject communicates to researchers that he wants more information of a particular sort than the reasonable person would, there is an obligation of the researcher to give that additional information, if the subject is to continue to be part of the experiment.⁵⁰ At least for non-therapeutic experiments, it ought to be sufficient for the researcher to drop such a subject from the research. For potentially therapeutic experiments the abandonment of the patient/subject by the physician/researcher when he or she has a treatment potentially beneficial to the patient/subject would raise the same problems of any physician abandonment. The obligation to give ample notice and reference of another physician willing to provide the treatment might be

required--at least within the limits of reasonableness. That few other physicians may be capable of giving the experimental treatment makes the case even more difficult than the normal therapeutic situation.

The case of the patient/subject who communicates that he or she wants less information than the reasonable person would be a more difficult problem. Since I am contending that the principle of self-determination is the one which ought to be used in requiring informed consent, it might be possible to argue that the patient/subject should have the right to determine that there is some information he or she would rather not have. That, of course, does not make the patient/subject's request for less information an ethical request. If the human is ethically responsible for decisions about his or her own medical future, it can be seriously questioned at the ethical level whether one is justified in waiving information necessary to make a consent informed. Nevertheless in cases of routine patient care such a waiver might be taken as sufficient to relieve the physician of an obligation to disclose.

In case of experimentation, however, I am not convinced that conclusion can be reached. I would still oppose imposition of information on the subject against explicit instructions from the subject. The researcher has another option, however. The investigator can turn to other subjects. That would seem to me to be the preferable course.

If the standard for an adequately informed consent is the standard of the reasonable person (modified in cases when there is evidence the subject differs from that standard), we are still left with the question of substance:

what information must be transmitted? The exact content must be determined by reasonable representatives of the public on a case by case basis. Some basic elements of informed consent, however, spell out the kinds of information necessary. In addition to the six elements currently included in DHEW guidelines,⁵¹ there are some additional elements I believe a reasonable person would want to know before giving an adequately informed consent.⁵² These include:

1. A specific disclosure of the presence of a control group within the research design.⁵³
2. A statement of the "inconveniences" as well as the risks and discomforts.⁵⁴
3. Names of review and patient protection agents including the person in the institution and the person at the federal level who should be contacted if the subject has further questions about the experiment.
4. A statement of the basic rights of the subject. This should include not only the presently required statement of the right to withdraw without prejudice, but the right to access to the alternative treatments, mention of which is now presently required.
5. Explanation of who, if anyone, will be responsible for harms done to the subject. This should include an explanation of who, if anyone, will be responsible for both anticipated harms the risk of which was included in the consent, and negligent and non-negligent, but unanticipated harms.
6. An explanation of the right, if any, to continue receiving treatment found helpful to patient/subject.

In addition the current DHEW regulations prohibit "exculpatory language through which the subject is made to waive, or appear to waive, any of his

legal rights, including any release of the organization or its agents from liability for negligence."⁵⁵ I see no reason why the prohibition should be limited to liability for negligence. I would propose dropping the "for negligence" so that exculpatory language waiving or appearing to waive liability is prohibited whether it is liability for negligence or some other liability.

These new elements which I believe are necessary for a consent to be adequately informed should be added to those currently in the list of six elements in the DHEW guidelines. I also endorse many of the elements proposed by Robert J. Levine⁵⁶ including especially the requirement that there should be a clear invitation rather than a request or demand, that the subject be informed why he has been asked to participate in the study, and that there be a suggestion to the prospective subject that he or she might wish to discuss the proposed research with another before consenting. I believe I disagree with Levine's final element--consent to non-disclosure--but only in that he does not specify the limits of the non-disclosure. I shall discuss below such limits when considering research which could be destroyed if informed consent were obtained.

I also share Levine's skepticism with the "short form" of the written consent document.⁵⁷ The use of a short written form which has the subject affirm that items have been explained orally serves no useful purpose especially since a written version must be on file with the IRB. In some cases it leads to suspicion about what is actually communicated not necessarily because the researcher is not trusted, but because staff actually obtaining the consent may accidentally omit certain items. I also share

Levine's doubts about general consent forms for categorically related research. It also fails to provide evidence of the actual consent should litigation arise. I believe both short forms and general consent forms should be excluded as not assuring legally effective consent. I would thus favor deletion of paragraph 46.10(b) from the May 30, 1974, version of the DHEW policy.

Finally, there is one procedural problem in the mechanism of getting consent which I think needs correction. Whether a regular or a short written form is used, it seems to me to be too much to ask of a researcher that he negotiate the consent with the subject himself. The commitment of the researcher to the worthiness of the project and the justification of the risk on grounds of benefit to the subject and/or others is, or ought to be very high--or he ought not to undertake the project in the first place. The conflict of interest is too great for a normal person to bear.⁵⁸ I would favor the use of those with no direct involvement in the protocol to negotiate the consent with the potential subject. (An alternative might be the negotiation first with the researcher and then with one hired as an advocate for the opposition to the subject's participation.)

III. THE IMPLICATIONS OF THE SELF-DETERMINATION THEORY OF CONSENT

What then are the implications of the self-determination theory of informed consent for subjects in different research settings? The implications will depend upon the setting. In this final section I shall take up, first, subjects which I would call Group I subjects, competent non-institutionalized adult subjects receiving private medical care. Then I will turn to the implications of the self-determination principle for Group II subjects,

subjects whose capacity to consent is compromised in some way.

A. Group I Subjects

The theory that consent for participation in research is rooted in the principle of self-determination has implications first for those subjects ideally placed to give consent which is relatively free and informed. If we limit ourselves to Group I subjects for non-therapeutic research, i.e. subjects who are mentally competent, non-institutionalized, adults who receive health care through private channels, we have probably limited ourselves to the group most capable of exercising self-determination. Some implications are apparent even for this group.

First, if self-determination is the objective, then consent is necessary for research independent of the risk involved. Second, recognizing that self-determination is always a relative phenomenon, determining how much information will be necessary for autonomous decision-making insofar as the goal is promoting self-determination will have to be based on standards as close as possible to the subject's own. Normally this will mean the consensus of reasonable lay persons, but modified as necessary to bring the standard in line with ways in which the subject may be known to differ from the reasonable lay person.

Third, there may be limits to that to which the lay person may acceptably consent. This is a problem which I have not taken up because it takes us beyond the nature and definition of informed consent. Even though informed consent may be rooted in a theory of self-determination, there may be other constraints on participation in research beyond the right to self-

determination. In a society as thoroughly committed to individual liberty as ours is, those limits may be very broad, but there may nevertheless be limits.

Even John Stuart Mill in On Liberty recognized at least two limits to liberty. The first is harm to others.⁵⁹ It is unlikely that experiments could be banned when subjects give free and informed consent on the grounds that they would do harm to others, but such objections are conceivable, as for instance, a viral transduction experiment attempt to manipulate the human genetic code where both researcher and subject are adequately informed and willingly agree to participate in the study.

Although it is not generally recognized Mill also places a second limit on liberty: the limit of prohibiting surrender of one's own liberty.⁶⁰ It is possible that some free and informed consents by subjects of Group I would be seen as surrendering too much liberty, in volunteering to take great risk of death for marginally valuable results or volunteering for experimental brain manipulation, for instance. Such consents could be attacked as not truly free or not adequately informed, but the mandate of local review committees would permit such prohibitions even if the consent were considered free and informed. The committee must determine not only if there is informed consent, but independently, whether the risks to the subjects are adequately outweighed by the potential benefits to subject and/or others. If the right of self-determination for the competent, non-institutionalized adult is taken seriously, the instances where that right should be compromised on paternalistic grounds will be extremely limited

if not non-existent. Occasionally experimentation with free and informed consent might be rejected on the grounds that the subject's liberty cannot voluntarily be surrendered. For the most part, however, such rejection would have to be based on the state's role as protector of the welfare of its citizens. There are limits to liberty in our society--until recently men could be drafted to risk life and limb--but in even those cases the conscription was done in the name of protecting liberty itself. Blocking of experiments in which there is free and informed consent solely on the independent grounds of paternalism seems rarely, if ever, justified.

B. Group II Subjects

Although I recognize the dangers of overgeneralization, I would like to call all groups of subjects where the capacity to consent is problematic Group II subjects. I call them Group II because I believe they should be considered for human experimentation only in cases where research on the first group is impossible. For the most part I mean impossible; not merely inconvenient. If the foundation of informed consent is self-determination, then consent is impossible in cases where self-determination is impossible. In all cases of Group II subjects self-determination is either impossible or constrained.

1. Children

The clearest example of the impossibility to exercise self-determination is the very young child. In the small child consent has a very limited applicability because self-determination is very limited. I believe, for the most part, it is a mistake to speak of "proxy consent" for experiments in children. Rather we should make clear precisely what is at stake:

research without subject consent justified if at all on some other grounds. For therapeutic research on young children we must fall back on a principle which we have seen is highly suspect: the principle of patient-benefit. Because, by definition, therapeutic research proposes experimental treatments about which there is no consensus as to the benefits, it is never possible to justify such experiments on general patient-benefit grounds.

Parental "approval" or "selection"⁶¹ of subjects for such therapeutic research is essential for two reasons: first, under the norm of patient-benefit parents in their guardian role are obligated to serve the best interests of their children. They are in the best position to protect their interests.

Second, since in cases of therapeutic experiment there is no consensus about what would be in the child's best interest, parents are given very limited discretion to choose values upon which decisions may be made for their children. It is in this second role that parental approval takes on the aura of a consent. Parents in our society are given limited authority to exercise their own self-determination about the values of their offspring. They are permitted to select religious training, parochial education not valued by the majority, vegetarian or "organic" diet, and other values not generally shared by the ordinary person. In this one sense parental "consent" is the appropriate term. That parental consent is very limited is apparent from the willingness of courts to intervene if parental determination of values deviates very far from the social consensus, if, for instance, Amish parents were to choose no school rather than, as in the case of parents

choosing parochial education, a minority school.

One of the areas in which parents are permitted to exercise some discretion is in encouraging the child to make minor contributions to the general welfare or the welfare of specific others. Parents may encourage the child to contribute a small portion of his allowance to the Red Cross, for instance. The limits of parental discretion are quite narrow, however. The child is not the property of the parent. Non-therapeutic research may be one area where parental self-determination is to be tolerated within these narrow limits.

One main line of opinion holds that no child or other non-consentable can ever be the subject of non-therapeutic research because he cannot consent, and a human should never be treated as a means rather than an end unless consent is obtained.⁶² This, however, is a highly individualistic understanding of individual responsibility. If in addition to being an end in himself with inalienable rights, the individual is seen as a member of a social community, then certain obligations to the common welfare may be presupposed even in cases where consent is not obtained. The dangers of balancing individual rights with obligations to serve the common welfare are great especially in cases where consent cannot be used as a mechanism to judiciously waive those rights. In very special cases, however, where truly no risk or minimal risk to the subject is envisioned and when information to be obtained from non-therapeutic experiments on children would be of great value which can be obtained in no other way, there must be some contribution to the general welfare which can be expected without consent

which the reasonable person would find required. This is not to say that social benefits can cancel individual rights, that patient benefit can be traded interchangeably for social benefit. It is rather to say that it is reasonable to treat the individual, nonconsenting subject as a means to an end under very limited and circumscribed conditions.

Even if it is emphasized that this is not the same as making the utilitarian trade off, there are great dangers in such a proposal. For this reason, parental approval of non-therapeutic research in such special cases should be required first, as the best check to make sure that individual rights are not unduly compromised and, second, to permit parental self-determination to be decisive in deciding whether their offspring will make a justifiable, but nonconsenting contribution to the general welfare.⁶³

All of this is said with regard to consent and parental approval for very young children where no self-determination is possible. It seems to me to be valid also for older children when potentially therapeutic experimenting is contemplated. There are two special problems, however. For children old enough to communicate when non-therapeutic experimenting is contemplated consent is possible although consent which may be neither free nor informed. Since the child has nothing to gain, it seems reasonable that his uninformed refusal should nevertheless be determinative. In addition to free and informed parental approval and the constraints on that approval (for the reasons given above) uninformed consent of the child should also be required in non-therapeutic experiments.

Finally for therapeutic experiments for older youth, some real self-determination may be possible.⁶⁴ If a youth could exercise self-determination, I see no reason why that should not take precedence over parental judgment. The problem, of course, is determining that the youth's judgment is free and informed. Two solutions seem possible: generally lowering the age of majority so that youth can consent on their own or making such judgments on a case by case basis. For some medical treatments lowering the age of consent for the particular treatment (such as venereal disease and birth control services) may be justified. In general, however, I think it is wiser to keep the age of consent for medical treatment high--at least 18. To adopt a general lower age for consent for medical treatment might mean substituting the persuasion of the medical profession or others with influence, for the authority of the parent. For therapeutic experimenting and for treatments not covered by a specific statute lowering the age for consent, case by case adjudication of the judgment of the youth disagreeing with parental judgment seems appropriate.

2. Formerly Competent Adults

Formerly competent adults--mental patients, the comatose, and the senile--are, for purposes of consent very similar to children in that they lack the capacity to exercise self-determination. They differ, however, in several important regards. First, since they are formerly competent, at one time in the past they could exercise self-determination. In some instances formerly competent individuals may have expressed disapproval of experimental cancer treatments or expressed a desire to contribute to scientific knowledge of their particular disease. While in children the

parental judgment about what is in the child's interest would be taken as decisive within limits, in the case of the formerly competent adult the situation is more complex. There is currently great debate about whether statements about medical treatments written while competent ought to remain valid when one is no longer competent.⁶⁵ Some argue that if the incompetent patient were able to have an opinion now when he is incompetent, his opinion would have changed; that it is impossible for the healthy individual to anticipate the experience of terminal illness or chronic mental incapacity. On the other hand, what judgment could be more reliable about the wishes of the now incompetent one? I take it to be an assault on the right to self-determination of the competent one to hold statements made while competent as unacceptable expressions of the best estimate of what one would want when and if incompetent.

There is a second problem with incompetents lacking in the case of children. While statute normally specifies when a child is a minor incapable of giving consent for medical treatment and research, the definition of incompetency in adults is much more tenuous. The circle defining those who are incompetent is shrinking rapidly. Many patients including some committed to mental institutions formerly considered incompetent to accept or refuse medical treatments are now being permitted to do so.

An institutionalized woman in depression was permitted to refuse the continuation of electroshock therapy.⁶⁶ A 60-year-old committed schizophrenic was permitted to refuse a breast biopsy for diagnosis of a possible malignancy on the grounds that she might die, that it would interrupt her

movie career, and prohibit her from having further children.⁶⁷ In New York the state Health Code explicitly specifies that mental patients are permitted to refuse experimental treatments.⁶⁸ Non-therapeutic experiments on mental patients should be under the same restrictions as for youth. In rare cases where they might be justified when the information cannot be gained in any other manner, when there is no risk or minimal risk, when there has been informed approval by a guardian, and uninformed pro forma consent by the subject. Therapeutic experiments ought to be conducted under consent conditions similar to those on a youth. Guardian approval or judicial determination that the patient is exercising adequate self-determination ought to be required. Expressions made while competent, however, should be taken as evidence of the patient/subject's wishes. Whether to permit pro forma refusal by the patient to be decisive over against guardian approval as is required in New York I find a difficult question. In general, though, the New York policy seems acceptable since by definition the benefits are problematic.

C. Prisoners

Although prisoners are frequently grouped with children and mental patients as difficult cases when discussing consent, the problems created in the case of prisoners are radically different. It is frequently noted that prisoners may not be free psychologically because of the coercive nature of the choices offered in the prison setting. It seems to me the only solution to that constraint on the prisoner exercising self-determination in consenting to participate in experiments is the restructuring of the institution so that the choice to participate in experiments is more on a par with other options. This might require increasing income opportunities from

other forms of prison employment. The only proposal which I find plausible within the present prison structure is that those wanting to do prison research pay to the prisoners--as a group--fees comparable to what it would cost to obtain subjects outside of prison while the individual subject would receive an amount determined to be proportionate to other income producing opportunities considering risk and time involved. The difference could then be used by the prison population for educational or recreational purposes of their own choosing.⁶⁹

The larger problem for consent prison research from the perspective of a self-determination theory of consent seems to me to be in a different area. In contrast with children, the senile, and the mentally incompetent, there is no reason to presume that prisoners lack the capacity for self-determination. If self-determination is a fundamental right in our society, then we should be very cautious in infringing upon that right even in the name of protecting the individual's welfare. While prisoners do not lack the capacity to consent, however, a social judgment has been made that their right to self-determination should be greatly constrained. Depending upon one's theory of imprisonment infringing upon self-determination is thought justified either for protection of the public interest, for rehabilitation, or for punishment for previous wrongs done. Thus the prisoners general presumptive right to self-determination has been compromised.

The implication for prisoner consent depends upon the theory of imprisonment. If the sole purpose of imprisonment is to protect the public--to get the criminal off the streets--then it is hard to see why the prisoner's

right to consent to research should in any way be compromised in principle. For rehabilitation exercise of the right ought to be encouraged. If, however, retribution is the basis of the imprisonment conceivably that right could be limited. If one of the functions of prison research is to give the prisoner an opportunity to make amends for previous wrong to society and to regain his sense of personal worth, then some might argue that such a "privilege" should not be given. That may be the view of the American Medical Association in their statement in 1952 in which they state:

...Whereas, some of the inmates who have participated have not only received citations, but have in some instances been granted parole much sooner than would otherwise have occurred, including several individuals convicted of murder and sentenced to life imprisonment... Resolved, that the House of Delegates of the American Medical Association express its disapproval of the participation in scientific experiments of persons convicted of murder, rape, arson, kidnapping, treason, or other heinous crimes, and also urges that individuals who have lost their citizenship by due process of law be considered ineligible for meritorious or commendatory citation....⁷⁰

Regardless of whether human beings are imprisoned for purposes of protection or retribution, I cannot accept this argument for depriving them of self-determination in consenting to experimentation. While some constraints on self-determination may be necessary, those constraints must be carefully circumscribed. There can be no general loss of basic human rights. Until recently being a prisoner brought what was called "civil death," the loss of all rights. That radical infringement of rights has been abandoned, however, in favor of a much more limited deprivation of rights. Self-determination in choices about medical treatment--including

experimental treatment--and about making humanitarian acts ought not to be limited any more than it would be for other competent adults. If constraints are necessary because prisoner consent is feared to be de facto coerced--even when the economic incentive is removed--that is a failure of the system which ought not to be attributed to any deprivation of the prisoner's right to self-determination in this area. It is particularly serious if prisoners are deprived of their right to potentially therapeutic experimental treatments for this reason.

4. Clinic Patients

Like prisoners, clinic patients do not in principle lack the capacity to consent, but may be coerced into consenting because of serious constraints on their options for receiving health care. I believe that clinic patients--patients whose opportunities to self-determination may be limited although their capacity should not be--should be treated as Group II subjects just as children, the mentally incompetent, and prisoners are. However, since they do not lack the capacity to consent and their rights would especially be jeopardized if they are deprived of any opportunity to participate in therapeutic research, I reject what at first seems plausible: banning of all research on clinic patients. Rather I would favor as a check on de facto coercion a general requirement that at least half of all subjects be drawn from sources other than clinic patients.

5. Subjects in Experiments Where Consent Would Destroy the Research

There is a final group of subject's whose right to self-determination is potentially compromised: subjects in experiments where getting informed consent would necessarily destroy the experiment. Research in psychology

of perception where the design requires deceiving the subject as to the purpose or procedures would be an example. An experiment to test the difference in response between subjects receiving a placebo in a drug study who are told there is a placebo in the design and those who are not told would be another.

First, it is important to distinguish between cases where consent would necessarily destroy the experiment and cases where it would simply make the experiment more difficult. Omitting consent for the convenience of the researcher seems to me to be never tolerable. Further, in some cases it may be possible to be clever in designing protocols so that deception or other lack of informed consent would not be necessary. In some cases it is believed that consent would destroy the experiment without any adequate grounds for that belief. For instance, I know of no evidence that telling subjects there is a placebo in the design of a drug study (never, of course, telling them whether they are receiving the placebo) would harm the experiment. It is possible that the reports from the subjects would be different--they may be more cautious in their reporting; but I know of no convincing argument that the results obtained would be any less valuable. In fact it could be argued that they would be more valuable, because the subjects would generally be on guard to make accurate reports. I believe that in all designs where a placebo is used, it should be a requirement of informed consent to state that there is a placebo in the design.

There will still, however, be research which cannot be done without deception of the subject. We have seen that current DHEW requirements

justify such omissions of informed consent.⁷¹ We deduced that a principle of social-benefits was necessary to omit consent in such cases. But not just any social benefit would justify the consent omission. That is clear in the DHEW guidelines. First, omissions are justified only when the consent would "surely invalidate objectives of considerable immediate importance," when "reasonable alternative means for attaining these objectives would be less advantageous for the subjects, and when the risk to any subject is minimal." Thus there is already a clear recognition that not just any social benefit is sufficient to waive the consent. In fact the requirement that reasonable alternative means for attaining these objectives would be less advantageous for the subject is a requirement which would possibly permit some therapeutic research deception, but would apparently prohibit all psychological studies using deception in normal subjects since the deception study is of no advantage to the subject whatsoever.

I think simultaneously we need to go further and have gone too far. I believe we may have gone too far if we rule out all deceptive experiments where only the good of society is at stake. At the same time we have not gone far enough in specifying what principles and what tests would justify waiving of the consent. Hans Jonas, in discussing non-disclosure in cases where disclosure would destroy the research, also takes a position that the subject's rights may be violated even though no harm is done: "Only supreme importance of the objective can exonerate it, without making it less of a transgression. The patient is definitely wronged even when not harmed."⁷² Jonas seems to limit his argument to non-disclosure in cases of research on patients (which he calls "an outright betrayal of trust"). It seems,

however, that the argument works equally for the non-patient subject.

Jonas also does not develop the argument about what would be sufficient to justify such a non-disclosure. It seems to me that the one instance where such non-disclosure would be justified, the one principle which would justify violating the right to self-determination, must be rooted in the concepts of self-determination and trust themselves. If, and only if, there is good empirical evidence that the subject would not consider the deceptive withholding of information a violation of that trust, would I find the non-disclosure acceptable.⁷³ If, and only if, we can reasonably presume on the basis of specific empirical evidence that reasonable subjects would not have objected to participating in the experiment without their consent, would such omission be justified.⁷⁴ I believe that is an empirically testable proposition. I would suggest that for any experiment which would be destroyed if informed consent were obtained, researchers should be required to draw a sample from the subject population proposed in the protocol, explain to these mock-subjects the research in mind including the benefits as well as the deception involved. Subjects should then be asked whether they would have considered their right to self-determination violated--whether they would have objected to being an uninformed participant, had the research actually been done on them without their informed consent. If we can predict, based on that sample, using a reasonable confidence limit such as 95 percent that other subjects drawn from the same population would not object, then it seems to be a justifiable compromise of the real subjects' right to self-determination. It is indeed a compromise because even at that level of certainty one subject in twenty

predictably would object to being made part of the experiment. Nevertheless this seems to me to be a reasonable compromise. If a lesser number of mock-subjects, say only a majority, approved, that could hardly justify a presumption that all or virtually all of the uninformed subjects would have approved of the deception.

The Need for Special Review of Consent in Group II Subjects

Because consent with all group II subjects is problematic procedures are needed to assure that these subjects' right to self-determination is not violated--insofar as such capacity exists. I would favor a special second level review of all research involving Group II subjects, a national board charged with reviewing all protocols using the same criteria as local boards. There is good reason to suppose that Group II subjects, especially clinic patients, are now used as subjects because their use is the path of least resistance. Establishment of an additional level of review would provide additional incentive to use subjects whose capacity and/or opportunities to consent is not as problematic. There is sufficient evidence that local committees vary tremendously in their standards for approving consents, that such precaution seems necessary to protect the rights and welfare of these special groups of subjects whose ability to give effective informed consent is so problematic.

The August 23, 1974, draft of proposed regulations for protection of human subjects includes an alternative to a national level review of consent.⁷⁵ That draft proposed additional protection for research involving fetuses, abortuses, pregnant women, and in vitro fertilization. It was proposed that a local "consent committee" be established to monitor consents.

The proposal could be expanded to cover all of what I have called Group II subjects. I favor such a committee and am disappointed that it was dropped from the policy adopted August 8, 1975.⁷⁶ The argument given against such committees--that it would cost too much in time, money, and social benefits--cannot be a definitive argument for jeopardizing the rights of subjects unless one is committed to a utilitarian calculus of social costs and benefits.⁷⁷ This argument, put forward by a distinguished group of researchers should at least not be taken as definitive by the representatives of the public since researchers are legitimately expected by society to have a unique value commitment to the social benefits of the research enterprise.

My own position, however, is not that the consent committees would impede social progress; I am not convinced that they would stand in the way of well designed and executed research. Rather I am concerned that a second group completely independent of the special characteristics institutionalized into the local IRB and exposed sufficiently to the special problems of consent in problematic cases be given an opportunity to review the quality of the consent as well as the judgment that the jeopardy to the subject's interests, rights and welfare is justified by the potential benefit to the subject and/or others. I would see this most effectively done by a national committee. This seems to me to be a compromise preferable to the well articulated and often reasonable demands that research be banned entirely on children, prisoners and other Group II subjects.

In principle I see one ground other than the principle of self-

determination which would justify experiments on human subjects. This would apply to all experiments including experiments requiring non-disclosure. It is often held, I believe correctly, that humans have a prima facie obligation to promote justice independent of the consequences. This has led to an exciting contemporary debate about the meaning of justice. The theory developed by John Rawls⁷⁸ and the more egalitarian variants of that theory⁷⁹ would consider some practices fair and even right which might deprive individuals of their right to self-determination. The justification, however, is not in the production of good social consequences on balance, but in promoting justice. I believe a theory of informed consent could be derived from this theoretical work which would provide a very limited basis for sacrificing the rights and interests of the individual for the benefit of certain others who are less well off (but not society in general).⁸⁰ I have purposely not developed such a formulation for this paper, relying instead on a theory of self-determination because I am not convinced that the theoretical work on the theory of justice is sufficiently advanced that it could be incorporated into practical public policy making by the National Commission without the risk of errors which would jeopardize the rights of individual subjects. I see the development of the implications of this theory for informed consent an important research problem for the next few years.

I am convinced that biomedical and behavioral research, both therapeutic and non-therapeutic, is of tremendous importance to the individual and to society. In fact, we might reasonably speak of the individual's right to such research. To do so, however, involves a recognition that fundamental rights, especially the individual's right to autonomy or self-

determination, which must provide the basis for free and informed consent. To fail to get such consent will do far more than jeopardize important benefits to the individual and to society, it will jeopardize those fundamental rights themselves.

¹Department of Health, Education and Welfare, Office of the Secretary, "Protection of Human Subjects," Federal Register 39 (number 105) Part II, May 30, 1974, pp. 18914-18920. See especially paragraph 46.2, p. 18917.

²In fact I would stand with those who favor even more caution in getting consent for clinical care and so-called therapeutic experiments than non-therapeutic research because of the strong, sometimes coercive, interest a sick person has in maintaining the approval of medical professionals. See Robert J. Levine, "The Nature and Definition of Informed Consent in Various Research Settings," December 1, 1975, paper prepared for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereafter cited as "Nature and Definition").

³The alternative is to pack the requirements that consent be free and informed into the definition of consent. The Oxford English dictionary has as its first definition "voluntary agreement to or acquiescence in what another proposes or desires; compliance, concurrence, permission." The ambiguity is apparently within the word itself. The first part of the definition includes the requirement of voluntariness while the latter synonyms do not. I prefer defining consent as the naked permission leaving to the adjectives to specify that adequate consent must be free and informed. I believe that adds clarity and functionally leads reviewers to the proper questions to ask about a particular consent.

⁴Hippocrates, The Sacred Disease, in W.H.S. Jones, ed., English edition Hippocrates II, p. 134.

⁵Ibid.

⁶Ludwig Edelstein, "The Hippocratic Oath: Text, Translation, and Interpretation" in Ancient Medicine (Johns Hopkins Press, 1976), pp. 3-63.

⁷The oath states the patient-benefitting principle twice, first with regard to dietic measures (one of the three elements of Pythagorean medicine): "I will apply dietetic measures for the benefit of the sick according to my ability and judgment." Later a more general form of the patient benefit-principle is repeated, this time without the explicit statement that the standard is to be the physician's own judgment, although this time the notion of intention is introduced: "Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice..." See text in Edelstein, ibid., p. 6.

⁸In addition to the fact that the patient-benefitting principle, if taken seriously, excludes all experimentation not done in the interests of the patient, it can also be criticized as being excessively individualistic (concentrating only on benefit to the individual, isolated patient) and paternalistic (using the physician's own judgment as the standard of reference). That it focuses exclusively on benefits and harms to the exclusion of other ethical questions such as right and obligations inherent in action, is a problem we shall discuss below.

⁹It has been recognized that in special circumstances so-called non-therapeutic research might be undertaken on healthy subjects in the name of patient-benefit. If an individual were at high risk to a particular disease testing a vaccine on that person in the face of an epidemic might be justified on the grounds that the risk to the patient himself was less in conducting the trial of the vaccine than in letting the patient go unprotected. (See Paul Ramsey, The Patient as Person (New Haven: Yale University Press, pp. 15-16.) Here, however, the principle of patient-benefit remains the norm. The judgment to include the patient in the test is made on strictly patient-benefitting grounds without consideration of benefit to others which might come from the knowledge gained.

¹⁰See Robert J. Levine's paper for the National Commission for the Protection of Human Subjects for a more extensive discussion of the distinction between therapeutic and non-therapeutic research.

¹¹Here I must explicitly reject the argument that some procedures undertaken where the two objectives of benefitting the patient and gaining knowledge both are present should not be seen as experimental. Bernard M. Dickens, for instance, argues that "If no orthodox treatment exists for the patient's condition (either because of the condition's novelty or because the orthodox treatment has become discredited by advances in medical knowledge) the physician's innovation will be nonexperimental." (Bernard M. Dickens, "What is a Medical Experiment?", Canadian Medical Association Journal 113 (Oct. 4, 1975), pp. 635-639, quotation from p. 636.) That seems to me to simply be a flagrant corruption of the term "experiment." It is one thing to say that under these circumstances there is no known better alternative; it is another to say that the trial of an unproved treatment is not experimental. Especially since he believes that a lower standard of consent may be required when a treatment is not experimental (a position which I reject in any case), much is at stake in the definitional debate. Certainly the patient ought to have the option of doing nothing in these circumstances, an option which by definition has not been shown to be any worse than the novel therapy.

¹²"Food and Drug Administration: Consent for Use of Investigational New Drugs (IND) on Humans--Statement of Policy," text in Jay Katz, Experimentation with Human Beings (New York: Russell Sage Foundation, 1972) p. 573. The same wording is reaffirmed in "Food and Drug Administration: Drugs for Human Use: Reorganization and Republication," Federal Register, (March 29, 1974), pp. 11684-11685 and 11712-11718.

¹³Department of Health, Education and Welfare, The Institutional Guide to DHEW Policy on Protection of Human Subjects (Washington: U.S. Government Printing Office, 1971), p. 8.

¹⁴"Protection of Human Subjects: Proposed Policy," Federal Register 38 (Part II, October 9, 1973).

¹⁵"Protection of Human Subjects," Federal Register 39 (Part II, May 30, 1974).

¹⁶It has long been recognized that it may be reasonable to persist in requiring that a rule such as the informed consent rule be followed even in individual cases where it appears that more good would come if the rule is violated. This is justified either on the grounds that the human being is sufficiently fallible that the rule is more likely to produce good on balance than individual judgment is or on the grounds that it is the nature of rules that they specify practices, practices which in turn might be chosen because they will produce more good than any other social practice. See John Rawls, "Two Concepts of Rules," Philosophical Review 64 (1955), pp. 3-32.

¹⁷See Ralph J. Alfidi, "Informed Consent: A Study of Patient Reaction," Journal of the American Medical Association 216 (May 24, 1971), pp. 1325-29, for empirical evidence.

¹⁸I recognize that the argument about consent in cases where the consent would do more harm than good implies that there may in fact be such cases. I am not prepared to concede that there are. If one recognizes that lack of consent per se may do harm--the patient may have unallayed fears, confusion about what behaviors are appropriate, etc.--then a case might be made that consent is always necessary on patient-benefitting grounds. For this discussion I presume, hypothetically, that consent might be contraindicated in some therapeutic experiment on patient-benefitting grounds.

Charles Fried in his important new discussion of the ethical foundations of experimentation develops the theme of "personal care" as the duty of the physician. (Charles Fried, Medical Experimentation: Personal Integrity and Social Policy (New York: American Elsevier Publishing Co., Inc., 1974). At one point he uses a qualified argument of "therapeutic privilege," that is the argument that information could be withheld on grounds of patient benefit (p. 22). Later, however, when he develops the theme of "personal care" he makes the claim that personal care involves a notion of rights which belong to the patient which seem to be independent of consequences. These rights include "a right to know all relevant details" (p. 101), autonomy, trust, and "the right to be treated without deceit or violence (p. 103). If, however, Fried perceives these to be rights inherent in personal care, it is hard to see how the physician has the "privilege" of overriding them when he believes (rightly or wrongly) that the overriding would be therapeutic. Therapeutic "privilege," if it exists at all, must be precisely that, a privilege the physician acquires because the patient has ceded the rights Fried has outlined.

¹⁹American Medical Association Judicial Council, Opinions and Reports of the Judicial Council (Chicago: A.M.A., 1971), pp. 11-12. Also see in addition to section 2 which commits the physician to improve medical knowledge, sections 1, 4, 9, and 10 where the physician is explicitly committed to serving society or other collective groups as well as the individual patient.

²⁰See Jeremy Bentham, An Introduction to the Principles of Morals and Legislation; John Stuart Mill, Utilitarianism; G.E. Moore, Principia Ethica, London: Cambridge University Press, 1903; and Henry Sidgwick, The Methods of Ethics, London: Macmillan and Co., Ltd., 1907.

²¹William Harvey, Exercitatio Anatomica de Motu Cordis et Sanguinis in Animalibus, 1628. Also see Henry E. Sigerist, "William Harvey's Position in the History of European Thought," in On the History of Medicine (New York: MD Publications, 1960), pp. 184-192.

²²Chauncey D. Leake, ed., Percival's Medical Ethics (Huntington, New York: Robert E. Krieger Publishing Co., 1975), p. 76.

²³Claude Bernard, An Introduction to the Study of Experimental Medicine, (New York: Dover, 1957), p. 102. Bernard certainly has gone further than even the classical utilitarians in claiming that experiments which may do good are obligatory. They would not be according to the utilitarians unless all things considered they would be likely to do more good than any other courses of action. Bernard, contrary to some interpretations of the negative formulation of the physician's duty primum non nocere (first, do no harm) seems to treat harms and benefits on the same scale.

²⁴This function corresponds to the point made by Katz and Capron that one purpose of informed consent is "to involve the public." Jay Katz and Alexander Morgan Capron, Catastrophic Diseases: Who Decides What? (New York: Russell Sage Foundation, 1975) p. 90; cf. Levine, "The Nature and Definition," p. 3.

²⁵"Protection of Human Subjects," Federal Register 39 (Part II, May 30, 1974), p. 18919.

²⁶See Carl J. Wiggers, "Human Experimentation as Exemplified by the Career of Dr. William Beaumont," in Clinical Investigation in Medicine: Legal, Ethical and Moral Aspects edited by Irving Ladimer and Roger W. Newman (Boston: Law-Medicine Research Institute, Boston University, 1963), pp. 119-125.

²⁷St. Martin bound himself to "Serve, abide and continue with the said William Beaumont, wherever he shall go or travel or reside in any part of the world his covenant servant and diligently and faithfully... submit to assist and promote by all means in his power such philosophical or medical experiments as the said William shall direct or cause to be made on or in the stomach of him, the said Alexis, either through and by

means of the aperture or opening thereto in the side of him, the said Alexis, or otherwise, and will obey, suffer and comply with all reasonable and proper orders of or experiments of the said William in relation thereto and in relation to the exhibiting and showing of his said stomach and the powers and properties thereto and of the appurtenances and the powers, properties and situation and state of the contents thereof." Text from William Beaumont, Experiments and Observations on the Gastric Juice and the Physiology of Digestion, 1833, cited in Henry Beecher, Research and the Individual: Human Studies (Boston: Little Brown, 1970), p. 219.

²⁸See Michael R. LaChat, "Utilitarian Reasoning in Nazi Medical Policy: Some Preliminary Investigations," Linacre Quarterly 42 (Feb. 1975), pp. 14-37; for an important discussion of the general problems of utilitarian justification of human experimentation see Ruth Macklin and Susan Sherwin "Experimenting with Human Subjects: Philosophical Perspectives," Case Western Reserve Law Review 25 (1975), pp. 434-471.

²⁹"The experiment is to be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature."

³⁰"1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity." In Jay Katz, Experimentation with Human Beings, op. cit., p. 305.

³¹See the interesting discussion in Bernard M. Dickens, "Contractual Aspects of Human Medical Experimentation," University of Toronto Law Journal 25 (1975), pp. 406-438.

³²*Carpenter v. Blake* 60 Barb. 488 (N.Y. Sup. Ct. 1871).

³³*Jackson v. Burnham* 20 Colo. 532 Pac. 577 (1895).

34Schloendorff v. New York Hospital 211 N.Y. 127, 129, 105 N.E. 92, 93 (1914), text in Jay Katz, op. cit., p. 526.

35Natanson v. Kline 186 Kan. 393 P2d 1093 (1960) text cited in Jay Katz, op. cit., p. 533.

36Fortner v. Koch 272 Mich. 272 N.W. 762 (1935).

37"Protection of Human Subjects," Federal Register 39 (Part II, May 30, 1974), p. 18917.

38I concede that someone with imagination might argue that there are indirect, but serious risks--that mankind's respect for the genetically abnormal would change and that, in turn, would have a psychological impact on the subject. If those risks are included, however, it seems that any research would have risks and the proviso "if risk is involved" is meaningless.

It seems more plausible to say that the subject is not really at risk in the normal sense of the term, but that the rights and welfare of others are and that that is sufficient reason why some might want to refuse to consent to participate in the study.

39I endorse Robert J. Levine's emphasis on explaining the "larger ultimate purpose" as well as the immediate one. See Levine, "The Nature and Definition," p. 10.

40See Immanuel Jakobovits, Jewish Medical Ethics (New York: Bloch Publishing Co., 1959), pp. 132-152; Fred Rosner, Modern Medicine and Jewish Law (New York: Yeshiva University Press, 1972), pp. 132-154; and David Bleich, "Medical Experimentation Upon Severed Organs," in his "Survey of Recent Halakhic Periodical Literature," Tradition 12 (Summer 1971), pp. 89-90.

41See L.C. Epstein and L. Lasagna, "Obtaining Informed Consent: Form or Substance," Archives of Internal Medicine 123 (1969), pp. 682-688.

42There are a number of variants on the professional standard: what is customary for physicians in the community to disclose, what physicians more generally in society or in a specialty group would disclose, or what the "reasonable physician" would disclose. All rely on a professional standard. See Leonard L. Riskin, "Informed Consent: Looking for the Action," University of Illinois Law Forum 1975 (number 4, 1975), pp. 580-611, especially pp. 585-586.

43Natanson v. Kline 186 Kan. 393 P. 2d 1093 (1960), cited in Jay Katz, op. cit., p. 534.

44California, Idaho, New York, Ohio, Oregon, Pennsylvania, Rhode Island, Washington, Wisconsin, and Tennessee, but cf. Karp v. Cooley, 349 F. Supp. 827 (S.D. Tex. 1972, affirmed 493 F. 2d 408 (5th Cir. 1974).

⁴⁵Riskin, op. cit. Also see Don Harper Mills, "Whither Informed Consent?" Journal of the American Medical Association 229 (July 15, 1974), pp. 305-309, where Mills concludes (p. 305) that "the 'standard of practice' basis for judging the extent of disclosure will probably give way to a new rule of reasonableness; though what the courts believe to be reasonable disclosure may not necessarily be consistent with what physicians believe should be disclosed."

⁴⁶Garnham, op. cit., pp. 143-44. Many, including Garnham, still maintain that although informed consent of patient or subject is impossible, some consent should still be obtained. There seems to be an inconsistency in this position.

^{46a}Of course, the same point can be made on patient- or subject-benefitting grounds if one holds that determining what is beneficial to the patient/subject is dependent upon the subject's own values. The fact that the researcher or the research community would find some piece of information irrelevant given the researcher's values or the values of the research community as a whole, cannot be taken to imply that it would be irrelevant in another value context.

⁴⁷Berkey v. Anderson, 1 Cal. App. 3d 790, 805, 82 Cal. Rptr. 67, 78 (1969).

⁴⁸The implications of the reasonable person court decisions for the composition of human experimentation committees and the questions they must answer is explored in greater detail in Robert M. Veatch, "Human Experimental Committees: Professional or Representative?" Hastings Center Report 5 (October 1975), pp. 31-40.

⁴⁹Norman Fost, "A Surrogate System for Informed Consent," Journal of the American Medical Association 233 (Aug. 18, 1975), pp. 800-803.

⁵⁰This Interpretation differs slightly from that of Robert J. Levine, "The Nature and Definition," p. 19. He says that the reasonable person standard "puts the particular physician or investigator in the precarious position of having to know in advance what harms a particular patient or subject might consider material after they occur." I agree that the physician is placed in a precarious position, but I do not think it is quite that precarious. My reading of the case law is that the physician must simply disclose what the reasonable person would find meaningful or useful. This should be modified when the physician has reason to believe that the individual patient or subject differs from that reasonable person view, but, unless the physician has negligently or maliciously avoided the discovery that the individual patient differs from the reasonable person, I do not see that he would be held to the standard of that (deviant) patient or subject. Of course, the physician is still in a precarious position because this series of cases makes clear that the physician's own judgment or even the consensus of medical professionals cannot be

taken to adequately predict what the reasonable person would want to know. This does mean, however, that an all lay committee made up of individuals reasonably presumed to be reasonable would be a plausible test of the adequacy of the information, unless there was information to the contrary about the individual subject. Levine goes on (p. 20) to introduce the reasonable person standard, but without qualifying it for the case when the researcher knows or should know that the subject differs from that reasonable person.

⁵¹"Protection of Human Subjects," Federal Register 39 (Part II, May 30, 1974), p. 18917.

⁵²For a fuller discussion of these elements see the author's "Ethical Principles of Medical Experimentation," in Ethical and Legal Issues of Social Experimentation edited by Alice M. Rivlin and P. Michael Timpane (Washington: The Brookings Institution, 1975), pp. 21-59, especially pp. 52-57.

⁵³See a fuller discussion of this issue below.

⁵⁴The specific mention of "inconveniences" occurs in the Nuremberg Code. Its omission has been taken as justifying non-disclosure of inconveniences by some review committee members although "inconveniences" could be taken to be subsumed in "risks." That "discomforts" is listed as separate from "risks" can be cited to support the claim that "inconveniences" are not to be taken as risks.

⁵⁵"Protection of Human Subjects," Federal Register 39 (Part II, May 30, 1974), p. 18918, paragraph 46.9.

⁵⁶Robert J. Levine, "The Nature and Definition," pp. 10, 11, 25.

⁵⁷Levine, ibid. , p. 57. Cf. "The Protection of Human Subjects," Federal Register 39 (Part II, May 30, 1974), p. 18919.

⁵⁸See Louis Lasagna, The Conflict of Interest Between Physician as Therapist and as Experimenter, (Philadelphia: Society for Health and Human Values, 1975).

⁵⁹John Stuart Mill, On Liberty (New York: Liberal Arts Press, 1956), p. 114, where he argues "for such actions as are prejudicial to the interests of others, the individual is accountable and may be subjected either to social or to legal punishment if society is of opinion that the one or the other is requisite for its protection."

⁶⁰Ibid., p. 125.

⁶¹This is the term preferred by Alexander Morgan Capron, "Legal Considerations Affecting Clinical Pharmacological Studies in Children," Clinical Research 21 (1972), pp. 141-150.

⁶²Paul Ramsey, op. cit., chapter 1.

⁶³The argument here is related to Richard McCormick's in "Proxy Consent in the Experimentation Situation," Perspectives in Biology and Medicine 18 (Autumn 1974), pp. 2-20.

⁶⁴G. Emmett Raitt, "The Minor's Right to Consent to Medical Treatment: A Corollary of the Constitutional Right of Privacy," Southern California Law Review 48 (1975), pp. 1417-1456.

⁶⁵In Re the matter of Karen Quinlan: an alleged incompetent: Superior Court of New Jersey, Chancery Division, Morris County, Docket No. C-201-75; Winters v. Miller, 446 F. 2d 65 (C.A.2, May 26, 1971).

⁶⁶New York City Health and Hospitals Corporation and Edward A. Stolzenberg, Associate Director, Bellevue Hospital, Petitioners, v. Paula Stein, a patient, respondent, 335 N.Y.S. 2d 461.

⁶⁷In re appointment of a guardian of the person of Maida Yetter, Docket No. 1973-533 (Pa. Ct. of Common Pleas, Northampton Co. Orphan's Ct., June 6, 1973).

⁶⁸N.Y. State Mental Hygiene Law, Article 15, "Rights of Patients," Section 15.03, Point (b)4.

⁶⁹I have heard this suggested in personal communication with Karen Lebacqz and, independently, by Roy Branson. Whether the system would work I do not know. Possibly prison officials or dominant prisoners would gain control of the funds in some cases leading to their inequitable use. Also it is not clear why drug companies and others wanting to do research would choose prisoners as subjects under these conditions. In order to get subjects in a controlled environment for long periods of time they might recruit students who would agree to spend weeks in a controlled institution in exchange for offerings of summer school courses, room and board at the researchers' expense. Whether an offer to an economically deprived group such as students would be seen as less coercive than for prisoners, I do not know, but at least institutional review and control might be more dependable and the danger of use of research for retribution would be eliminated.

⁷⁰American Medical Association House of Delegates, "Resolution on Disapproval of Participation in Scientific Experiments by Inmates of Penal Institutions," text in Henry Beecher, op. cit., p. 225. This position may also be rooted in the concern for protecting the public interest insofar as research participation leads to earlier release from prison. It would not directly justify opposition to meritorious or commendatory citation, however.

⁷¹We have already argued that the positions of private groups of professionals should not be persuasive in setting public policy. They are often committed to special value stances not shared by the general public. Thus the acceptance of the American Psychological Association

of deception and even lying--presumably on the justification of the social benefits to be obtained--should not be terribly relevant to the Commission. The Association's unique commitment to the social value of the particular type of knowledge gained should not influence commissioners who have a public obligation to protect constitutionally guaranteed rights. See American Psychological Association, Ethical Principles in the Conduct of Research With Human Participants (Washington, A.P.A., 1973), pp. 29-35; Cf. Code of Ethics, American Sociological Association, which says obliquely, "Just as sociologists must not distort or manipulate truth to serve untruthful ends, so too they must not manipulate persons to serve their quest for truth."

⁷²Hans Jonas, Philosophical Essays (Englewood Cliffs, New Jersey: Prentice Hall, 1974), p. 126.

⁷³See the qualification of this statement related to a possible theory of justice below.

⁷⁴I believe this a more explicit principle and more precise requirement than Levine advocates. See Levine, "The Nature and Definition," p. 30.

⁷⁵"Protection of Human Subjects: Proposed Policy," Federal Register, August 23, 1974, pp. 30653-30654.

⁷⁶"Protection of Human Subjects: Fetuses, Pregnant Women, and In Vitro Fertilization," Federal Register, August 8, 1975, pp. 33526-33552. I also support third party scrutiny proposals as set forth by Levine, op. cit., pp. 46-52. However I feel such third parties should be used only with the consent of the subject. Discussing the proposed research first with the next of kin and/or a physician not connected with the research is certainly a violation of the individual's right to confidentiality. It should be clear, however, that third parties must be independent of the researcher and his or her staff. Thus the debate between Don Harper Mills and Alan Meisel over whether the physician or nurses and physician assistants associated with them would be better witnesses of the consent may be misplaced. While certainly the physician or researcher cannot be an adequate witness of a consent contract between himself and the patient or subject, those working under his supervision would not be adequate either. See Alan Meisel, "Informed Consent--The Rebuttal," Journal of the American Medical Association 234 (Nov. 10, 1975), p. 615; and Don Harper Mills, "Informed Consent--The Rejoinder," Journal of the American Medical Association 234 (Nov. 10, 1975), p. 616.

⁷⁷"Position Statement of the American Federation for Clinical Research on the DHEW Proposed Rules on Protection of Human Subjects," Clinical Research 23 (1975), pp. 53-60.

⁷⁸John Rawls, A Theory of Justice, (Cambridge, Mass.:Harvard University Press, 1971).

⁷⁹See Brian Barry, The Liberal Theory of Justice (New York: Oxford University Press, 1973); and Robert M. Veatch, "What Is a Just Health Care Delivery?," in Ethics and Health Policy edited by Robert M. Veatch and Roy Branson (Cambridge, Mass.: Ballinger Press, forthcoming).

⁸⁰See Macklin and Sherwin, op. cit.

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